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Primary & Secondary
Healthcare Department

MINUTES OF MEETING OF THE GRIEVANCE REDRESSAL COMMITTEE HELD ON 20th JULY, 2022 AT 11:00 A.M. TO REDRESS THE GRIEVANCE APPLICATIONS OF THE FIRMS AGAINST TECHNICAL EVALUATION OF PREQUALIFICATION APPLICATIONS FOR THE PREQUALIFICATION OF DRUGS/MEDICINES, DIRECTORATE GENERAL HEALTH SERVICES, PUNJAB, FY 2022-23

A meeting of the Grievance Redressal Committee was held on 20-07-2022 at 11:00 A.M in committee room of Directorate General Health Services, Punjab, to address the grievances of the applicants, as per Rule 67 of Punjab Procurement Rules, 2014 (Amended), for Prequalification of Drugs/Medicines, Directorate General Health Services, Punjab, FY 2022-23.

Following members of Grievance Redressal Committee attended the meeting:

Sr.	Participants	
1.	Director Health Services (HQ), DGHS	Chairman/Convener
2.	Director Health Services (HQ) O/o Director General Health Services, Punjab	Member
3.	Additional Director Medical (Admin) O/o Director General Health Services, Punjab	Member
4.	Senior Law Officer O/o Director General Health Services, Punjab	Member
5.	Director Pharmacy O/o Director General Health Services, Punjab	Member

The Chair welcomed all the participants and briefed about agenda of meeting i.e. Grievance Redressal of firms against Prequalification Technical Evaluation Report for the Prequalification of Drugs/Medicines, Directorate General Health Services, Punjab, FY 2022-23.

The Chair instructed the representatives of aggrieved firms to come one by one serial wise so that proper hearing/ redressal of grievance may be ensured. The grievances of firms and decisions of grievance redressal committee are as follow:

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
1	57	Cefixime Capsule/Tablets 400mg	AGP Limited	Cinklare 400mg Capsule	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>	<p>1. Calibration Certificate of Stability Chambers 2. Undertaking against clause # 6 Sample of quoted products never declared sub-standard (not over 5%) 3. Undertaking against clause # 7 "Daily production capacity of quoted item" is attached with notarization & attestation 4. Undertaking against clause # 8 "Batch capacity of quoted items" is attached with notarization & attestation 5. Undertaking against clause # 16 "Firm follows Labour Laws" is attached with notarization & attestation We are submitting our documents for your kind perusal. Kindly consider our application for prequalification.</p>	<p>Mr. Yasir Ali, Distributor of M/s AGP Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
2	58	Cefixime Suspension 100mg/5ml	AGP Limited	Cinklare 100mg/5ml Suspension	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>	<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
3	59	Cefixime Suspension 200mg/5ml	AGP Limited	Cinklare 200mg/5ml Suspension	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
4	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	AGP Limited	Rigix Oral 5mg/5ml 120 ml Solution	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
5	68	Cetirizine Tablets 10mg	AGP Limited	Rigix 10mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
6	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	AGP Limited	Algocin 500mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
7	118	Escitalopram Tablets 10mg	AGP Limited	Esi-Dep 10 mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
8	121	Folic Acid Tablets 5mg	AGP Limited	Novafol 400 mcg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

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9	126	Glimepiride Tablets 2mg	AGP Limited	Gluconorm 2mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
10	148	Iron Sucrose Injection 100mg/5ml	AGP Limited	Rubiject 100mg/5ml Injection	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
11	184	Montelukast 4mg Dry Powder sachet	AGP Limited	Lucast 4mg Sachet	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

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12	185	Montelukast Tablets 10 mg	AGP Limited	Lucast 10mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
13	219	Phloroglucinol Hydrate 40mg + Trimethyl Phloroglucinol 0.04mg Injection	AGP Limited	Anafortan Plus 0.04mg/40 mg Injection	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		The firm did not contest for the quoted item.
14	220	Phloroglucinol Hydrate 80mg + Trimethyl Phloroglucinol 80mg tablets	AGP Limited	Anafortan Plus 80mg/80mg Tablets	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

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15	269	Tramadol HCl Injection 100mg/2ml	AGP Limited	Calфина 100 mg/2ml Injection	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
16	270	Tranexamic Acid Capsules 500mg	AGP Limited	Maxna 500mg Capsules	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
17	271	Tranexamic Acid Injection 500mg/5ml	AGP Limited	Maxna 500mg Injection	Not Qualified	<p><u>Firmwise</u> Clause No. 12: Calibration/validation certificate/record of Stability Chambers not Attached. Clause No.16: Undertaking not notarized.</p> <p><u>Itemwise</u> Clause No.7: Daily production capacity of quoted item not attached Clause No. 8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided Calibration certificates of Stability Chambers, which were accepted. Clause No.16: The firm provided requisite undertaking on notarized stamp paper, which was accepted.</p> <p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

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18	149	Isoflurane Liquid Inhalation 100ml	Allied Distributors	Restane	Not Qualified	<u>Firmwise</u> Clause No.6: FBR income tax return/sales Tax return for the year 2018-19, 2019-20 not attached.	Item No. 149 Isoflurane Liquid and Item No. 247 Sevoflurane Liquid As per the Clause No. 6 Minimum Financial turnover for any single financial year we M/s Allied Distributors had attached Sales Tax Returns FY 2020-2021 along with Bank Statement (Signed and stamped by the Bank) on Page # 35 - 120. We are sending you the said documents again for your kind consideration. Item No. 232 Propofol 200 mg As per the Clause No. 6 Minimum Financial turnover for any single financial year we M/s Allied Distributors had attached Sales Tax Returns FY 2020-2021 along with Bank Statement (Signed and stamped by the Bank) on Page # 35 - 120. We are sending you the said documents again for your kind consideration. We had attached MHLW, GOVERNMENT OF JAPAN on Page # 135 – 141 as an evidence of Quality Compliance Standard of the Product. We are sending you the said documents again for your kind consideration. We had attached Valid Sole Agency Agreement on Page # 143 – 146. We M/s Allied Distributors are authorized sole agent of Dongkook Pharmaceutical Co., Ltd since 2002. We are sending you the said documents again for your kind consideration along with Previous Sole Agency Agreement.	Mr. MirzaJaved Baig, Sales Manager from M/s Allied Distributors attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.6: The firm provided FBR income tax return/sales Tax return for the year 2018-19, 2019-20, which were accepted.
19	232	Propofol 200 mg Injection 200mg/20ml	Allied Distributors	Pofol	Not Qualified	<u>Firmwise</u> Clause No.6: FBR income tax return/sales Tax return for the year 2018-19, 2019-20 not attached. <u>Itemwise</u> Clause No.3: Quality Compliance Standards Certificate not Attached. Clause No.8: Valid Sole agency agreement of quoted item is not at least previous one year till the last date of submission of PQD.		<u>Firmwise</u> Clause No.6: The firm provided FBR income tax return/sales Tax return for the year 2018-19, 2019-20, which were accepted. <u>Itemwise</u> Clause No.3: The firm did not provide Quality Compliance Standards certificate of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No.8: The firm provided Valid Sole agency agreement of quoted item at least previous one year till the last date of submission of PQD, which was accepted.
20	247	Sevoflurane Liquid Inhalation 250ml	Allied Distributors	Sojourn	Not Qualified	<u>Firmwise</u> Clause No.6: FBR income tax return/sales Tax return for the year 2018-19, 2019-20 not attached.		<u>Firmwise</u> Clause No.6: The firm provided FBR income tax return/sales Tax return for the year 2018-19, 2019-20, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
21	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	ALLMED PVT LTD	A-CIP	Not Qualified	<p><u>Itemwise</u> Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>	<p>In technical evaluation report following deficiency were pointed by your esteemed institution and declared us non responsive - 01- (Item wise) Product serial no 173,198,385,253,300,245- Clause No.7: Daily production capacity of each quoted item not mention on stampaper. Clause No.8: Maximum Batch size of each quoted item not mentioned on stampaper. 02- (Item wise) Product serial no 245 Clause No.2: DRAP approval of quoted pack size is not attached On response we are going to submit our review request along with supporting documents. In first we want to bring in your kind notice that our undertaking on stampaper of our daily production capacity with detailed paper attached at Annexure (16) of submitted file. Secondly same as our undertaking on stampaper of our Maximum Batch Size with detailed paper attached at Annexure (17) of submitted file. Now we are going to submit our grievance application with 01- Undertaking of Daily Production Capacity with complete details at one page stampaper – 02- Undertaking of Maximum Batch Size with complete details at one page stampaper 03- DRAP approved pack size of our quoted item no 245</p>	<p>Mr. Muhammad Ismail, Director Plant from M/s Allmed Pvt. Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: Itemwise Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>
22	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	ALLMED PVT LTD	AVENAC	Not Qualified	<p><u>Itemwise</u> Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>	<p>Itemwise Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>	

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23	107	Domperidone 10mg Tablet	ALLMED PVT LTD	Gastroke	Not Qualified	<p><u>Itemwise</u> Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>		<p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>
24	147	Iron iii Hydroxide Polymaltose Syrup	ALLMED PVT LTD	HEMFIL	Not Qualified	<p><u>Itemwise</u> Clause No. 2: DRAP approval of quoted pack size not attached. Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>		<p><u>Itemwise</u> Clause No.2: The firm provided DRAP approval of 120ml Pack, which was accepted. Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>

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25	154	Levofloxacin Tablet 250mg	ALLMED PVT LTD	LEVOGRE EN	Not Qualified	<p><u>Itemwise</u> Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>		<p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>
26	201	Ondansetron injection 4mg/2ml	ALLMED PVT LTD	ANOMED	Not Qualified	<p><u>Itemwise</u> Clause No. 7: Daily production capacity of each quoted item not mentioned on Stamp Paper. Clause No.8: Maximum Batch size of quoted item is not mentioned on Stamp Paper.</p>		<p><u>Itemwise</u> Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted. During the course of meeting, the representative of the firm admitted himself that the Minimum Annual financial turnover of Allmed (Pvt) Ltd. for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees. Therefore, Allmed (Pvt) Ltd. does not comply with firmwise clause no. 14; hence, grievance of the firm regarding consideration of Annual financial turnover of its subsidiaries/sister concern was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
27	19	Amoxicillin (trihydrate) Capsules/tablets 250mg	Amros Pharmaceuticals	AMFAST 250MG CAPSULE	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.	We are submitting herewith required documents for your consideration. S.No. Attached Documents 45. DRC & Renewals + Undertaking for Production Capacity and Batch Size 46. DRC & Renewals + Undertaking for Production Capacity and Batch Size 49. DRC & Renewals + Undertaking for Production Capacity and Batch Size 50. DRC & Renewals + Undertaking for Production Capacity and Batch Size 51. DRC & Renewals + Undertaking for Production Capacity and Batch Size 54. DRC & Renewals + Undertaking for Production Capacity and Batch Size 55. DRC & Renewals + Undertaking for Production Capacity and Batch Size 56. DRC & Renewals + Undertaking for Production Capacity and Batch Size 60. DRC & Renewals + Undertaking for Production Capacity and Batch Size 61. DRC & Renewals + Undertaking for Production Capacity and Batch Size 47. Undertaking for Production Capacity and Batch	Mr. Hamza Imran, Distribution Manager from M/s Amros Pharmaceuticals attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause No. 2: The firm provided trail of registration renewal of the quoted item, which was accepted. Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.
28	20	Amoxicillin (trihydrate) Capsules/tablets 500mg	Amros Pharmaceuticals	AMFAST 500MG CAPSULE	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.	Size 48. Undertaking for Production Capacity and Batch Size 52. Undertaking for Production Capacity and Batch Size 53. Undertaking for Production Capacity and Batch Size 57. Undertaking for Production Capacity and Batch Size 58. Undertaking for Production Capacity and Batch Size 59. Undertaking for Production Capacity and Batch Size 62. Undertaking for Production Capacity and Batch Size 63. Undertaking for Production Capacity and Batch	<u>Itemwise</u> Clause No. 2: The firm provided trail of registration renewal of the quoted item, which was accepted. Clause No.7: The firm provided Daily production capacity of quoted item on notarized stamp paper, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item on notarized stamp paper, which was accepted.
29	23	Amoxicillin + Clavulanic Acid Suspension 125 mg + 31.25 mg / 5 ml	Amros Pharmaceuticals	CLAV DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.	Size 64. Undertaking for Production Capacity and Batch Size 65. Undertaking for Production Capacity and Batch Size 66. Undertaking for Production Capacity and Batch Size 67. Undertaking for Production Capacity and Batch Size 68. Undertaking for Production Capacity and Batch Size 69. Undertaking for Production Capacity and Batch	<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
30	24	Amoxicillin + Clavulanic Acid Suspension 250mg+62.5mg/5ml	Amros Pharmaceuticals	CLAV DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.	Size 70. Undertaking for Production Capacity and Batch Size 71. Undertaking for Production Capacity and Batch Size 72. Undertaking for Production Capacity and Batch Size 73. Undertaking for Production Capacity and Batch Size	<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
31	25	Amoxicillin + Clavulanic Acid Tablets 625 mg	Amros Pharmaceuticals	CLAV 625MG TABLET	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm provided trail of registration renewal of the quoted item, which was accepted. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
32	27	Amoxicillin Suspension 125mg/5ml	Amros Pharmaceuticals	AMFAST 125MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
33	28	Amoxicillin Suspension 250mg/5ml	Amros Pharmaceuticals	AMFAST 250MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm provided trail of registration renewal of the quoted item, which was accepted. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
34	41	Azithromycin Capsules/Tab 250mg	Amros Pharmaceuticals	AMROZEE 250MG CAPSULE	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
35	43	Azithromycin Susp 200mg/5ml	Amros Pharmaceuticals	AMROZEE 200MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
36	57	Cefixime Capsule/Tablets 400mg	Amros Pharmaceuticals	ROFIL 400MG CAPSULE	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
37	58	Cefixime Suspension 100mg/5ml	Amros Pharmaceuticals	ROFIL 100MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
38	59	Cefixime Suspension 200mg/5ml	Amros Pharmaceuticals	ROFIL 200MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
39	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Amros Pharmaceuticals	RITEXONE 1G INJECTION I.V	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
40	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Amros Pharmaceuticals	RITEXONE 250MG INJECTION I.V	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
41	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Amros Pharmaceuticals	RITEXONE 500MG INJECTION IV	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
42	64	Cephadrine Capsule 500mg	Amros Pharmaceuticals	VOLVOCE F 500MG CAPSULE	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
43	66	Cephadrine Susp 125mg/5ml	Amros Pharmaceuticals	VOLVOCE F 125MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
44	69	Chloramphenicol Ear Drops 1% w/v	Amros Pharmaceuticals	CHLORAMPHENICOL 1% EAR DROPS	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
45	70	Chloramphenicol Eye Drops 0.5% w/v	Amros Pharmaceuticals	CHLORAMPHENICOL 0.5% EYE DROPS	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
46	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Amros Pharmaceuticals	AMROCIP 500MG TABLET	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
47	81	Clarithromycin Suspension 125mg/5ml	Amros Pharmaceuticals	KLARIM 125MG/5ML DRY SUSPENSION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
48	82	Clarithromycin Tablets 500mg	Amros Pharmaceuticals	KLARIM 500MG TABLET	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
49	92	Dexamethasone sodium phosphate Injection 4mg/ml, ampoule/vial of 1ml	Amros Pharmaceuticals	DEXAMET HASONE 4MG/ML INJECTION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
50	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Amros Pharmaceuticals	AMROFEC 50MG TABLET	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
51	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Amros Pharmaceuticals	AMROFEC 75MG/3ML INJECTION	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
52	109	Doxycycline (hyclate) Capsules 100mg	Amros Pharmaceuticals	DOXYCYC LINE 100MG CAPSULE	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
53	154	Levofloxacin Tablet 250mg	Amros Pharmaceuticals	LEMEN 250MG TABLET	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
54	199	Omeprazole Capsule 20mg	Amros Pharmaceuticals	ROLAZ 20MG CAPSULE	Not Qualified	Itemwise: Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
55	208	Paracetamol Syrup/Susp 160mg /5ml or less.	Amros Pharmaceuticals	SAVPOL 120MG/5ML SUSPENSION	Not Qualified	Itemwise: Clause No. 2: DRC Renewal is not attached. Clause No. 7: Daily production capacity of each quoted item is not on Stamp Paper. Clause No. 8: Maximum batch size of quoted item is not on Stamp Paper.		<u>Itemwise</u> Clause No. 2: The firm did not provide trail of registration renewal of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter. Clause No. 7: The firm provided Daily production capacity of quoted item, which was accepted. Clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
56	33	Anti-Snake venom Serum (ASV)	Amson Vaccines and Pharma (Private) Ltd	Snake Venom Antiserum	Not Qualified	<u>Itemwise</u> Clause no. 03: Quality Compliance Standards certificate of quoted product not attached.	Hakimsons (Snake Venom Antiserum) batch no. A05316014 & A05315062 by Bharat Serums and Vaccines Limited have been declared failed by CDLs of India and FDA Maharashtra had suspended the license of Bharat Serums for ASVS quality issues in stark violation of clause-5 (Any Spurious & adulterated samples of quoted item) of item wise knock Down Criteria for Sole Agents of Foreign Principal for Drug Medicine Items. Letters issued by respective CDLs of India are enclosed along with online screenshot as a proof for your kind reference. You are requested to declare Snake Venom Antiserum (inq.33) quoted by M/S Hakimsons as NOT QUALIFIED for violating the knock down clause-5 of item wise evaluation criteria.	Mr. Aqeel Nasir, Institutional Sales Manager of M/s Amson Vaccines and Pharma (Private) Ltd attended the meeting. In reference to grievance submitted by M/s Amson Vaccines and Pharma (Private) Ltd. The committee examined the documents submitted by M/s Hakimsons (Impex) (Private) Ltd in light of the grievance application submitted by M/s Amson Vaccines and Pharma (Private) Ltd. The decision of the committee after due deliberation and discussion are mentioned against quoted item of the said firm.
57	37	Atenolol Tablet 50mg	AsianContinental (Pvt.) Ltd.	Cardiolite Tablet 50mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached	Our firm has not been declared pre-qualified due to the reason "Clause no. 6: ISO 18001/45001 not attached" We want to clarify that as per pre-qualification documents Clause no 6 is read as "Valid ISO 18001/45001 (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS) / International Accreditation Forum (IAF) / International Accreditation Service (IAS) / Firm's (EHS) Policy implementation SOPs" So as an alternate to ISO 18001/45001 we have already provided on online portal & Hard copies and are providing again Firm's (EHS) Policy implementation SOPs as allowed in knockout criteria and has been accepted in previous years also. So, we request your kind authority to accept our grievance in this regard. Our products Diclofenac tab and diclofenac injection has been not accepted due to "Clause no. 2 DRAP approval of quoted pack not attached" We want to reiterate that the DRAP approval of quoted packs has been	Mr. Muhammad Taimoor, Distributor of M/s AsianContinental (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
58	38	Atorvastatin Tablets 20mg	AsianContinental (Pvt.) Ltd.	vasclear Tablet 20mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
59	41	Azithromycin Capsules/Tab 250mg	AsianContinental (Pvt.) Ltd.	Macrobac Capsules 250mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
60	42	Azithromycin Capsules/Tab 500mg	AsianContinental (Pvt.) Ltd.	Macrobac 500mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
61	43	Azithromycin Susp 200mg/5ml	AsianContinent al (Pvt.) Ltd.	Macrobac Suspension	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	uploaded before and submitted in hard copies but are attaching again so kindly approve our products. Our product azithromycin suspension has not been accepted due to "Samples Substandard of quoted item (over 5%)" We have made 94 number of batches since 01-01-2021 out of which 3 batches have been declared substandard (We have already given our reply to it therefore the percentage of substandard is less than 5%. We want to highlight that "Lactulose syrup" of Abbott Laboratories (Pakistan) Limited has been accepted. We want to mention that the lactulose syrup of Abbott Laboratories has been manufactured by Highnoon Laboratory Limited Lahore. Highnoon Laboratory Limited Lahore has not applied for pre-qualification of their product Lactulose syrup and nor the company has been pre-qualification, so as per our understanding the manufacturer of the product must be pre-qualified for the product to be pre-qualified.	<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted. <u>Itemwise</u> Clause no. 6: The firm could not justify its claim that Samples Substandard of quoted item (less than 5%) from (01-01-2021); hence, grievance of the firm was not accepted to the extent of this parameter.
62	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	AsianContinent al (Pvt.) Ltd.	Uzartil Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
63	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	AsianContinent al (Pvt.) Ltd.	Voren Tablet 50mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached <u>Itemwise</u> Clause no. 2 DRAP approval of quoted pack not attached.		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted. <u>Itemwise</u> Clause no. 2 The firm provided DRAP approval of 100's Pack, which was accepted.
64	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	AsianContinent al (Pvt.) Ltd.	Voren Injection 75mg/3ml	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached <u>Itemwise</u> Clause no. 2 DRAP approval of quoted pack not attached.		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted. <u>Itemwise</u> Clause no. 2 The firm provided DRAP approval of 100's Pack, which was accepted.
65	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	AsianContinent al (Pvt.) Ltd.	Voren 75mg Inj	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached <u>Itemwise</u> Clause no. 2 DRAP approval of quoted pack not attached.		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted. <u>Itemwise</u> Clause no. 2 The firm provided DRAP approval of 10's Pack, which was accepted.
66	109	Doxycycline (hyclate) Capsules 100mg	AsianContinent al (Pvt.) Ltd.	Contimycin Capsules 100mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached <u>Itemwise</u> Clause no. 2 Quoted specification does not comply with advertised specification. DRAP approval of quoted pack not attached.		The firm did not contest for the quoted item.
67	147	Iron iii Hydroxide Polymaltose Syrup	AsianContinent al (Pvt.) Ltd.	Feralife Syrup	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
68	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	AsianContinent al (Pvt.) Ltd.	Kolac Syrup 3.35gm/5ml	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
69	154	Levofloxacin Tablet 250mg	AsianContinent al (Pvt.) Ltd.	Asilix Tablet 250mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
70	160	Losartan Potassium Tablet 50mg	AsianContinent al (Pvt.) Ltd.	Losanta Tablet 50mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
71	171	Metformin (hydrochloride) Tablets 500mg	AsianContinent al (Pvt.) Ltd.	Meteor Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
72	185	Montelukast Tablets 10 mg	AsianContinent al (Pvt.) Ltd.	Juveyx Tablet 10mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
73	199	Omeprazole Capsule 20mg	AsianContinent al (Pvt.) Ltd.	Zolbi Capsules 20mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
74	270	Tranexamic Acid Capsules 500mg	AsianContinent al (Pvt.) Ltd.	Traxacid Capsules 500mg	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
75	271	Tranexamic Acid Injection 500mg/5ml	AsianContinent al (Pvt.) Ltd.	Traxacid Injection 500mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.
76	279	Vitamin D3 Injection 5mg	AsianContinent al (Pvt.) Ltd.	AC-D3 Injection	Not Qualified	<u>Firmwise</u> Clause no. 6: ISO 18001/45001 not attached		<u>Firmwise</u> Clause no. 6: Policy implementation SOP for ISO 18001, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
77	117	Erythropoietin 4000-5000 I.U Injection Vial/Pre-filled syringe	Aster Life Sciences	Epotiv Prefilled Injection 4000IU/0.4 ml	Not Qualified	<p><u>Firmwise</u> Clause no. 08: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." not as prescribed in the PQ Application documents.</p> <p><u>Itemwise</u> Clause no. 01: DRAP approval of quoted pack not attached. Clause no. 03: Quality Compliance Standard certificate not verified from official website of US FDA. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." not as prescribed in the PQ Application documents.</p>	<p>We are not convinced with the evaluation report as our firm has been declared "Not Qualified" by the Technical evaluation committee on following remarks; (Item No. 117 (Erythropoietin 4000IU)) Reason of disqualification. Firm wises Clause No 08: Undertaking " None of its supplied batch in public sector institutions has been declared spurious & Adulterated since last 3 years till the closing date of prequalification documents submission." Not as prescribed in the PQ Application documents. Item Wise Clause No 01 : DRAP approval of quoted pack not attached. Clause No 03: Quality Compliance standard certificate not verified from official website of US FDA Clause No 04 : Undertaking "Required storage temperature as per product's requirement" not as prescribed in the PQ Application documents. Justification. Firm wises We are sending herewith undertaking regarding : None of its supplied batch in Public sector institutions has been declared spurious & adulterated since last 3 years till the closing date of prequalification documents submission " Annex. 1 Item Wise DRAP Approval for quoted pack is attached for your kind perusal Annex. 2 Our quoted product is registered and being manufactured by FDA approved plant of LG Chem Ltd. Furthermore, Epotiv is being supplied to Turkey (CPP is attached for ready reference). Quality Compliance standard certificate of LG Chem Ltd is verifiable through FDA official portal. Furthermore, Korea is PICS member country like USA and other leading developed countries so quality standards of drugs/medicines being manufactured by Korean Pharmaceuticals companies are equal to developed countries. Please refer PICS/ WHO Compliance GMP certificate for LG Chem Ltd. Annexure 3 Undertaking to maintain required storage temperature of quoted item while transportation was</p>	<p>Mr. Munim Khan, Distributor of M/s Aster Life Sciences attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that:</p> <p><u>Itemwise</u> Clause no. 01: The firm provided DRAP approval of 3's Pack, which was accepted. Clause no. 03: The firm could not verify Quality Compliance Standard certificate from official website of US FDA; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in the PQ Application documents, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
78	183	Modified Fluid Gelatin 4% Infusion 500ml	B. Braun Pakistan Private Limited	GELOFUSINE	Not Qualified	<p><u>Firmwise</u> Clause no. 2: Undertaking of "Valid Sole Agency Agreement." not attached. Clause no. 6: FBR income tax return/sales Tax return for the year 2020 not attached.</p> <p><u>Itemwise</u> Clause no. 3: Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO (Certificate) of quoted item not attached.</p>	<p>In pre-qualification evaluation report of Medicine Category FTY 2022-23 issued on 01-07-2022, some short comings were highlighted against the following inquiry numbers: • Sole Agent Drug/Medicine Category Addendum(s): 183 & 232 We here by submitting all the required documents that may be the reason for noncompliance of our products. • Firm Wise: Clause No 2: Undertaking for providing valid sole agency agreement for B. Braun Melsungen AG Germany & B. Braun Medical Industries Sdn. Bhd Malaysia (attached) Clause No 6: FBR income tax return/sales tax return for the year 2020 (attached) • Item Wise: Clause No 03: Quality Compliance Standards (EMA. JMHLW, US FDA, Prequalified by WHO certificates for the item enquiry No 183 (GELOFUSINE) (attached) All above mentioned documents & some other supporting documents (see details in check list) are attached for your kind consideration. We M/S B. Braun Pakistan (Pvt.) Ltd. request you to please consider our documents and approve/ prequalify our quoted products for the said prequalification</p>	<p>Mr. from M/s B. Braun Pakistan Private Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 2: The firm provided undertaking of "Valid Sole Agency Agreement.", which was accepted. Clause no. 6: The firm provided FBR income tax return/sales Tax return for the year 2020, which were accepted. <u>Itemwise</u> Clause no. 3: The firm did not provide Quality Compliance Standards certificate (EMA/JMHLW/US FDA/prequalified by WHO (Certificate) of the quoted item; hence, grievance of the firm was not accepted to the extent of this parameter.</p>
79	232	Propofol 200 mg Injection 200mg/20ml	B. Braun Pakistan Private Limited	PROPOFOL LIPURO 1%	Not Qualified	<p><u>Firmwise</u> Clause no. 2: Undertaking of "Valid Sole Agency Agreement." not attached. Clause no. 6: FBR income tax return/sales Tax return for the year 2020 not attached.</p>	<p><u>Firmwise</u> Clause no. 2: The firm provided undertaking of "Valid Sole Agency Agreement.", which was accepted. Clause no. 6: The firm provided FBR income tax return/sales Tax return for the year 2020, which were accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
80	16	Amlodipine Tablets 5 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Ampress Tablet 5mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	We Barrett Hodgson Pakistan are renowned pharmaceutical manufacturing company having good alliance with Govt. and semi-Government institute for the supply of our quality products at economical rates. We Barrett Hodgson Pakistan Private Limited participated in DGHS Prequalification of drugs and medicine for FY 2022-22 and declared No-responsive against all quoted items due to Non-Provision of below mentioned documents. 1) FBR income Tax return/sales Tax return for the year 2019-20 and 2020-21 (attached) 2) Drug Registration Certificate of T.E No: 41, 42, 43, 156, 157, 249 (attached) 3) Item No 219 (Spasrid Injection) Daily production capacity/ batch size (attached) 4) Item No 185 (Aerokast Tab 10mg) not according to specifications (Prequalification report is attached of 2020-2021 as it was already qualified on the same specifications) We are submitting all above documents as per your requirements and request you to declare a Pre-qualified bidder to ensure healthy competition between bidders in procurement of medicine.	Mr. Shehzad Nisar, Deputy Commercial Director from M/s Barrett Hodgson Pakistan (Private) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
81	38	Atorvastatin Tablets 20mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Sensicon Tablet 20mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
82	41	Azithromycin Capsules/Tab 250mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Mazox Capsules 250mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted item not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRC of quoted item, which was accepted.
83	42	Azithromycin Capsules/Tab 500mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Mazox Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted item not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRC of quoted item, which was accepted.
84	43	Azithromycin Susp 200mg/5ml	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Mazox 200mg/5ml Dry Suspension	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted item not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
85	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Inocef I.V Injection 1000mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
86	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Inocef I.V Injection 250mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
87	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Inocef I.V Injection 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
88	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Gixer Oral Solution	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
89	68	Cetirizine Tablets 10mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Gixer Tablet 10mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
90	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Inoquin Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
91	78	Ciprofloxacin Ear Drops 0.3% w/v	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Cipotic Ear Drops	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
92	80	Ciprofloxacin Injection 200mg / 100ml	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Inoquin I.V Infusion	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
93	81	Clarithromycin Suspension 125mg/5ml	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Megaklar Suspension 125mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
94	82	Clarithromycin Tablets 500mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Megaklar Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
95	85	Clopidogrel Tablets 75 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Clotnil Tablet 75mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
96	88	Clotrimazole Vaginal tablet 500 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Barresten Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
97	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Mobikare Capsule 50mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
98	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Mobikare Injection	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
99	107	Domperidone 10mg Tablet	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Domel Tablet	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	
100	118	Escitalopram Tablets 10mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Seradep Tablet 10mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
101	126	Glimepiride Tablets 2mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Diabold Tablet 2mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
102	147	Iron iii Hydroxide Polymaltose Syrup	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Polyfer Syrup	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
103	148	Iron Sucrose Injection 100mg/5ml	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Ivefer Injection	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
104	154	Levofloxacin Tablet 250mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Dynaquin Tablet 250mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
105	156	Lignocaine (hydrochloride) 2% Injection	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Xyloaid Solution 2%	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted item not attached. DRAP approval of quoted pack not attached		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 50's Pack, which was accepted.
106	157	Lignocaine (hydrochloride) Topical forms 2% Gel	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Xyloaid Jelly 2%	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted item not attached. DRAP approval of quoted pack not attached		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 15gm Pack, which was accepted.
107	160	Losartan Potassium Tablet 50mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Sartan Tablet 50mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
108	184	Montelukast 4mg Dry Powder sachet	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Aerokast Sachet 4mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
109	185	Montelukast Tablets 10 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Aerokast 10mg Tablet	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no.02: Quoted specification does not comply with advertised specification.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no.02: Quoted specification does not comply with advertised specification; hence, grievance of the firm was not accepted to the extent of this parameter.
110	186	Moxifloxacin Eye drops 0.5%(5ml)	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Moxigan Eye Drops	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
111	208	Paracetamol Syrup/Susp 160mg /5ml or less.	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Febrol Suspension	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
112	219	Phloroglucinol Hydrate 40mg + Trimethyl Phloroglucinol 0.04mg Injection	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Spasrid Injection	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 7: daily production capacity of quoted item not attached. Clause no. 8: maximum batch size of quoted item in units not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 7: The firm did not provide daily production capacity of quoted item not attached; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 8: The firm did not provide maximum batch size of quoted item in units not attached; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
113	220	Phloroglucinol Hydrate 80mg + Trimethyl Phloroglucinol 80mg tablets	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Spasrid Tablet	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
114	249	Sitagliptin 50mg Tablet	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	S-Gliptin Tablet 50mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached. <u>Itemwise</u> Clause no. 2: DRC of quoted strength not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRC of quoted item, which was accepted.
115	268	Tramadol HCl Capsule/Tablet 50 mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Baritral Capsule 50mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
116	279	Vitamin D3 Injection 5mg	BARRETT HODGSON PAKISTAN (PRIVATE) LTD.	Bar D Injection	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return for the year 2019-20 and 2020-21 which were accepted.
117	86	Clotrimazole Skin cream 1% w/w	Bayer Pakistan (Pvt) Limited	Canesten Clotrimazole Cream	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return not attached.	We have been notified by your Institution to disqualified due to FBR income tax return / sales tax return were not attached. We would like to inform that we had submitted only top page of income tax return as per practice for tender submission. However, now complete sets of income tax return (ITR) are being submitted herewith. You are requested to excuse us and re-consider our applied products for technical qualification. Here we are enclosing all technical and supporting documents again.	Mr. Muhammad Ibrahim, Institutional Business Manager from M/s Bayer Pakistan (Pvt) Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return, which were accepted.
118	87	Clotrimazole Vaginal Cream 10%	Bayer Pakistan (Pvt) Limited	Canesten Vaginal Cream, with Applicator	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
119	88	Clotrimazole Vaginal tablet 500 mg	Bayer Pakistan (Pvt) Limited	Canesten 1 Vaginal Tablet, with Applicator	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income tax return/sales Tax return not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income tax return/sales Tax return, which were accepted.
120	117	Erythropoietin 4000-5000 I.U Injection Vial/Pre-filled syringe	BF Biosciences Limited	Eritrogen	Not Qualified	<u>Firmwise</u> Clause no.12: calibration/validation certificate/record of functional stability chambers not attached.	It is stated that our firm and its quoted products have been declared as "Not Qualified" based on the following parameter: Sr. No. 184 to 186: Firm-wise: Clause No. 12: calibration/validation certificate/record of functional stability chambers not attached. We would like to submit that: 1. At BF Biosciences calibration is performed "In House". As per cGMP guidelines Calibration can be "In House" or "Outsourced" if the following criteria are met. "Calibration of measuring and monitoring of equipment is achieved through calibration against a pre-calibrated standard having unbroken and traceable chain of calibration to the national calibration standards." Following documents have been attached which are self-explanatory and sufficient to substantiate our claim. 1- Calibration of Master Temperature Instrument, certificate No. 13653 from NPSL, Islamabad. 2- SOP for In-house Calibration (ENG.-SOP-035). 3- Calibration of In-House Master standard We, therefore, request you to please re-evaluate our firm's qualification application	Mr. Syed Ghous uddin Saif, Chief Operating Officer from M/s BF Biosciences Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chambers, which were accepted.
121	200	Omeprazole Injection 40mg	BF Biosciences Limited	Omega	Not Qualified	<u>Firmwise</u> Clause no.12: calibration/validation certificate/record of functional stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chambers, which were accepted.
122	211	Pegylated interferon alfa-2a	BF Biosciences Limited	Peg INF	Not Qualified	<u>Firmwise</u> Clause no.12: calibration/validation certificate/record of functional stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chambers, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
123	16	Amlodipine Tablets 5 mg	Bio Labs (pvt) Ltd	Amdol Tablets 5mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>	As per the report, our following products have been declared "Not Qualified". • Committee Remarks: Firm Wise: Clause no.12: Calibration / Validation Certificate / Record of Stability Chamber not attached. Item wise: Clause No 7: Daily Production of quoted item not attached. Clause No 8: Maximum batch size of quoted Item not attached These Clauses 12, 7, and 8 are said to be against the products below and declared as "not qualified". Inq. No. Item Name Quoted Brand Inq. No. Item Name Quoted Brand 16 Amlodipine Tablet 5mg Amdol 5mg 147 Iron III Hydroxy Maltose Complex eq. to Elemental Iron Merah Syrup 34 Artemether + Lumefantrine Suspension 15 + 90 mg Susp. Bio-Lumefar Dry Suspension 148 Iron Sucrose Iropas Ampoule 100mg 38 Atorvastatin Tablets 20mg Weistat Tablets 20mg 154 Levofloxacin as Hemihydrate 250mg F-oxacin 250mg Tablets 41 Azithromycin Capsules/Tab 250mg Throb 250mg Capsule 173 Metoclopramide (hydrochloride) Injection 10mg Metoclor Ampoule 10mg 42 Azithromycin Capsules/Tab 500mg Biozith 500mg Tablets 177 Metronidazole 500mg/100ml Metrozole Infusion 500mg/100ml 43 Azithromycin Susp 200mg/5ml Throb dry suspension 180 Miconazole 20mg Miconit Oral Gel 57 Cefixime Capsule/Tablets 400mg Biozil Capsule 400mg 185 Montelukast (as sodium) 10mg Monest Tablets 10mg 58 Cefixime Suspension 100mg/5ml Biozil Dry suspension 100mg/5ml 188 Nalbuphine Hydrochloride Bio-Nal Plus Ampoule 10mg 59 Cefixime Suspension 200mg/5ml Biozil Dry suspension 200mg/5ml 198 Ofloxacin 200mg O-oxacin Tablets 60 Ceftriaxone (Sodium) Injection 1gm IV Tuff Injection 1gm I/V 199 Omeprazole 20mg cap Acicheck Capsule 20mg 61 Ceftriaxone (Sodium) Injection 250mg IV Tuff Injection 250mg I/V 200 Omeprazole (as Sodium) Lyophilized Powder Acicheck 40mg Lyophilized Inj 62 Ceftriaxone (Sodium) Injection 500mg IV Tuff Injection 500mg I/V 213 Permethrin Cream Bioscab Cream 64 Cephadrine Capsule 500mg Biodine Capsule 500mg 214 Permethrin Lotion Bioscab Lotion 66 Cephadrine Susp 125mg/5ml Biodine Dry Suspension 248 Silver	Mr. Sheikh Inam, Sales Manager from M/s Bio Labs (pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
124	34	Artemether + Lumefantrine Suspension 15 + 90 mg Susp.	Bio Labs (pvt) Ltd	Bio-Lumefar Dry Suspension	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause no.2: DRAP approval of quoted pack not attached Clause No.7 : Daily production of quoted item not attached. Clause No.8: Maximum batch size of quoted item not attached.</p>	(hydrochloride) Injection 10mg Metoclor Ampoule 10mg 42 Azithromycin Capsules/Tab 500mg Biozith 500mg Tablets 177 Metronidazole 500mg/100ml Metrozole Infusion 500mg/100ml 43 Azithromycin Susp 200mg/5ml Throb dry suspension 180 Miconazole 20mg Miconit Oral Gel 57 Cefixime Capsule/Tablets 400mg Biozil Capsule 400mg 185 Montelukast (as sodium) 10mg Monest Tablets 10mg 58 Cefixime Suspension 100mg/5ml Biozil Dry suspension 100mg/5ml 188 Nalbuphine Hydrochloride Bio-Nal Plus Ampoule 10mg 59 Cefixime Suspension 200mg/5ml Biozil Dry suspension 200mg/5ml 198 Ofloxacin 200mg O-oxacin Tablets 60 Ceftriaxone (Sodium) Injection 1gm IV Tuff Injection 1gm I/V 199 Omeprazole 20mg cap Acicheck Capsule 20mg 61 Ceftriaxone (Sodium) Injection 250mg IV Tuff Injection 250mg I/V 200 Omeprazole (as Sodium) Lyophilized Powder Acicheck 40mg Lyophilized Inj 62 Ceftriaxone (Sodium) Injection 500mg IV Tuff Injection 500mg I/V 213 Permethrin Cream Bioscab Cream 64 Cephadrine Capsule 500mg Biodine Capsule 500mg 214 Permethrin Lotion Bioscab Lotion 66 Cephadrine Susp 125mg/5ml Biodine Dry Suspension 248 Silver	<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 30ml Pack, which was accepted. Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
125	38	Atorvastatin Tablets 20mg	Bio Labs (pvt) Ltd	Weistat Tablets 20mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>	<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
126	41	Azithromycin Capsules/Tab 250mg	Bio Labs (pvt) Ltd	Throb 250mg Capsule	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.	Sulphadiazine Bio-Sul Cream 77 Ciprofloxacin (Hydrochloride) 500mg tablet C-oxacin 500mg tablet 268 Tramadol HCL 50mg capsule Tremendovs Capsule 50mg 80 Ciprofloxacin (Hydrochloride) 200mg/100ml C-Oxacin infusion 269 Tramadol HCL 100mg ampoule Tremendovs ampoule 100mg 81 Clarithromycin Suspension 125mg/5ml Bioclar Dry Suspension 125mg/5ml 276 Vancomycin HCl 500mg Myvan Inj 500mg 82 Clarithromycin 500mg tablet Bioclar Tablets 500mg 279 Cholecalciferol (Vitamin D3) 5mg (eq 200,000IU of Vitamin D) Bio-D3 Injection 86 Clotrimazole 1% w/w Biotrim Cream 281 Water for Injection Aquabio Ampoule 10ml 100 Diclofenac Sodium 50mg Artecid 50mg Capsule 282 Water for Injection Aquabio Ampoule 5ml 101 Diclofenac Sodium 75mg ampoule Artecid Ampoule 75mg 107 Domperidone Maleate 10mg Omperin Tablets 10mg 118 Escitalopram E-Cital 10 mg Tablets 120 Fluconazole Flunaz 150mg Capsule 138 Ibuprofen Biofen Suspension Company's Narration: It is stated that we M/S Bio-Labs has submitted the complete documentation Record in both Forms (hard copy as well as uploaded in soft form). DRCs of products has not been attached: • Biozith 500mg Tab (Azithromycin) • Bio-Lumefar suspension (Artemether + Lumefantrine) Here we are again going to attach our undertaking's proof of these Clauses 12, 7, and 8 and DRC's We therefore request you to kindly reconsider the Documents and our products may kindly be declared as "Qualified" since they meet evaluation criteria parameters.	<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
127	42	Azithromycin Capsules/Tab 500mg	Bio Labs (pvt) Ltd	Biozith 500mg Tablets	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause no.2: DRAP approval of quoted pack not attached Clause No.7 : Daily production of quoted item not attached. Clause No.8: Maximum batch size of quoted item not attached.	86 Clotrimazole 1% w/w Biotrim Cream 281 Water for Injection Aquabio Ampoule 10ml 100 Diclofenac Sodium 50mg Artecid 50mg Capsule 282 Water for Injection Aquabio Ampoule 5ml 101 Diclofenac Sodium 75mg ampoule Artecid Ampoule 75mg 107 Domperidone Maleate 10mg Omperin Tablets 10mg 118 Escitalopram E-Cital 10 mg Tablets 120 Fluconazole Flunaz 150mg Capsule 138 Ibuprofen Biofen Suspension Company's Narration: It is stated that we M/S Bio-Labs has submitted the complete documentation Record in both Forms (hard copy as well as uploaded in soft form). DRCs of products has not been attached: • Biozith 500mg Tab (Azithromycin) • Bio-Lumefar suspension (Artemether + Lumefantrine) Here we are again going to attach our undertaking's proof of these Clauses 12, 7, and 8 and DRC's We therefore request you to kindly reconsider the Documents and our products may kindly be declared as "Qualified" since they meet evaluation criteria parameters.	<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 10's Pack, which was accepted. Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
128	43	Azithromycin Susp 200mg/5ml	Bio Labs (pvt) Ltd	Throb dry Suspension	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.	(Azithromycin) • Bio-Lumefar suspension (Artemether + Lumefantrine) Here we are again going to attach our undertaking's proof of these Clauses 12, 7, and 8 and DRC's We therefore request you to kindly reconsider the Documents and our products may kindly be declared as "Qualified" since they meet evaluation criteria parameters.	<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
129	57	Cefixime Capsule/Tablets 400mg	Bio Labs (pvt) Ltd	Biozil Capsule 400mg	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
130	58	Cefixime Suspension 100mg/5ml	Bio Labs (pvt) Ltd	Biozil Dry suspension 100mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
131	59	Cefixime Suspension 200mg/5ml	Bio Labs (pvt) Ltd	Biozil Dry suspension 200mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
132	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Bio Labs (pvt) Ltd	Tuff Injection 1gm I/V	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
133	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Bio Labs (pvt) Ltd	Tuff injection 250mg IV	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
134	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Bio Labs (pvt) Ltd	TUFF injection 500mg IV	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
135	64	Cephadrine Capsule 500mg	Bio Labs (pvt) Ltd	Biodine Capsule 500mg	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
136	66	Cephadrine Susp 125mg/5ml	Bio Labs (pvt) Ltd	Biodine Dry Suspension	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
137	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Bio Labs (pvt) Ltd	C-oxacin 500mg tablet	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
138	80	Ciprofloxacin Injection 200mg / 100ml	Bio Labs (pvt) Ltd	C-Oxacin infusion	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
139	81	Clarithromycin Suspension 125mg/5ml	Bio Labs (pvt) Ltd	Bioclar Dry Suspension 125mg/5ml	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
140	82	Clarithromycin Tablets 500mg	Bio Labs (pvt) Ltd	Bioclar Tablet 500mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
141	86	Clotrimazole Skin cream 1% w/w	Bio Labs (pvt) Ltd	Biotrim Cream	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
142	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Bio Labs (pvt) Ltd	Artecid 50mg capsule	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
143	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Bio Labs (pvt) Ltd	Artecid Ampuole 75mg/3ml	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
144	107	Domperidone 10mg Tablet	Bio Labs (pvt) Ltd	Omperin 10mg Tablet	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
145	118	Escitalopram Tablets 10mg	Bio Labs (pvt) Ltd	E-Cital 10mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
146	120	Fluconazole Capsules 150mg	Bio Labs (pvt) Ltd	Flunaz 150mg capsule	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
147	138	Ibuprofen Susp. 100mg/5ml	Bio Labs (pvt) Ltd	Biofen Suspension	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
148	147	Iron iii Hydroxide Polymaltose Syrup	Bio Labs (pvt) Ltd	Merah Syrup	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
149	148	Iron Sucrose Injection 100mg/5ml	Bio Labs (pvt) Ltd	Iropas amapuole	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
150	154	Levofloxacin Tablet 250mg	Bio Labs (pvt) Ltd	F-Oxacin 250mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
151	173	Metoclopramide (hydrochloride) Injection 10mg	Bio Labs (pvt) Ltd	Metoclor Ampuole 10mg	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
152	177	Metronidazole 500mg/100ml infusion	Bio Labs (pvt) Ltd	Metrozole infusion	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
153	180	Miconazole (Nitrate) 2% Oral gel	Bio Labs (pvt) Ltd	Miconit Oral Gel	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
154	185	Montelukast Tablets 10 mg	Bio Labs (pvt) Ltd	Monest 10mg Tablet	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
155	188	Nalbuphine Hcl Injection 10mg/ml	Bio Labs (pvt) Ltd	Bio-Nal Plus Ampuole	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
156	198	Ofloxacin 200mg Tablets	Bio Labs (pvt) Ltd	O-oxacin Tablet	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
157	199	Omeprazole Capsule 20mg	Bio Labs (pvt) Ltd	Acichek 20mg Capsule	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
158	200	Omeprazole Injection 40mg	Bio Labs (pvt) Ltd	Acichek 40mg Lyophilized Injection	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
159	213	Permethrin Cream 5%	Bio Labs (pvt) Ltd	Bioscab Cream	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
160	214	Permethrin Lotion 5%	Bio Labs (pvt) Ltd	Bioscab Lotion	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>
161	248	Silver Sulphadiazine Cream 1%	Bio Labs (pvt) Ltd	Bio-Sul Cream	Not Qualified	<p><u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached.</p> <p><u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.</p>		<p><u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted.</p> <p><u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
162	268	Tramadol HCl Capsule/Tablet 50 mg	Bio Labs (pvt) Ltd	Tremendov s Capsule	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
163	269	Tramadol HCl Injection 100mg/2ml	Bio Labs (pvt) Ltd	Tremendov s ampoule 100mg	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		The firm did not contest for the quoted item.
164	276	Vancomycin (HCl) Injection 500 mg	Bio Labs (pvt) Ltd	Myvan 500mg	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
165	279	Vitamin D3 Injection 5mg	Bio Labs (pvt) Ltd	Bio-D3 injection	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
166	281	Water for injection 10 ml Sterile	Bio Labs (pvt) Ltd	Aquabio Ampuole	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
167	282	Water for injection 5 ml Sterile	Bio Labs (pvt) Ltd	Aquabio 5ml injection	Not Qualified	<u>Firmwise</u> Clause No. 12: calibration/validation certificate/record of Stability Chambers not Attached. <u>Itemwise</u> Clause No.7 : Daily production of quoted item not attached. clause No.8: Maximum batch size of quoted item not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of Stability Chambers, which were accepted. <u>Itemwise</u> Clause No. 7: The firm provided Daily production of quoted item as prescribed in PQ Document, which was accepted. clause No. 8: The firm provided Maximum batch size of quoted item, which was accepted.
168	47	Betamethasone Cream 0.1%	Bloom Pharmaceutical s (Pvt) Ltd	Junate Cream	Not Qualified	<u>Itemwise</u> Clause No. 2: DRAP approval of quoted pack size not attached.	our grievance request is mentioned below in annotative form with reply of observations:- Sr. No Inq No Name of Medicines with remarks 235 57 Cefixime 400mg capsule pack of 5s Remarks:- Clause no 6: Sample standard of quoted item over 5% from 01-01-2021 Reply: It is submitted that our product Cefixime capsule 400mg (Sivarol) was declared Misbranded not Substandard by DTL Lahore. (copy attached) (Annex-I) The said mater was discussed in the recent meeting of Provincial Quality Control Board, held on 31-05-2022 in which a warning has been issued to our firm with the remarks to be careful in future. Order copy is placed at (Annex-II) It is further added here that we have manufactured 45 batches w.e.f 01-01-2021 to 30-06-2022 and supplied to Govt Sector and Private Sector. According to the Manufactured bathes the ratio of 5% is 2.25 batches. According to that ratio our sample standard is not over 5%. The copy of batch production history is attached herewith for ready reference. (Annex-III) Sr. No Inq No Name of Medicines with remarks 251 109 Doxycycline 100mg	The firm did not contest for the quoted item.
169	57	Cefixime Capsule/Tablets 400mg	Bloom Pharmaceutical s (Pvt) Ltd	Sivarol 400mg Capsule	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		Mr. Qaisar Iqbal, General Manager Sales from M/s Bloom Pharmaceuticals (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 45 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
170	109	Doxycycline (hyclate) Capsules 100mg	Bloom Pharmaceuticals (Pvt) Ltd	Doxyline 100mg Capsule	Not Qualified	<u>Itemwise</u> Clause 2: Quoted item did not comply with our advertised specification.	Capsule pack of 100s Remarks:- Clause no 2: Quoted item did not comply with our advertised specification Reply: It is submitted that our product Doxycycline 100mg was registered in 1998. At that time Hyclate was not written with Doxycycline. (Annex-IV) But we always use the raw material as Doxycycline hyclate	<u>Itemwise</u> Clause 2: The firm provided commercial unit pack of quoted item which specified the quoted specifications which comply with advertised specifications; hence, grievance of the firm was accepted to the extent of this parameter.
171	124	Gentamycin Injection 80mg	Bosch Pharmaceuticals (Pvt.) Ltd.	Gentic	Not Qualified	<u>Itemwise</u> Clause No.2 : DRAP approval of quoted pack not attached.	As per your findings the following items are not qualified, because of missing valid DRC of quoted items Item # 281 water for injection 10ml sterile. Item # 282 water for injection 5ml sterile. We are again submitted valid DRC of above mentioned items for your kind consideration and record.	The firm did not contest for the quoted item.
172	271	Tranexamic Acid Injection 500mg/5ml	Bosch Pharmaceuticals (Pvt.) Ltd.	Btrol	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.
173	281	Water for injection 10 ml Sterile	Bosch Pharmaceuticals (Pvt.) Ltd.	Water for Injection	Not Qualified	<u>Itemwise</u> Clause 2: Valid DRC of the quoted item not attached.		Mr. Haq Nawaz, Marketing Manager from M/s Bosch Pharmaceuticals (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause 2: The firm provided valid DRC of the quoted item, which was accepted.
174	282	Water for injection 5 ml Sterile	Bosch Pharmaceuticals (Pvt.) Ltd.	Water for Injection	Not Qualified	<u>Itemwise</u> Clause 2: Valid DRC of the quoted item not attached.	<u>Itemwise</u> Clause 2: The firm provided valid DRC of the quoted item, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
175	39	Atracurium (besylate) Injection 10mg/ml	Brookes Pharma Private Limited.	Acuron Injection	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.	Your Respected Technical Committee has declared our Quoted Products as "Not – Prequalified", detail is mentioned below: (PRODUCT LIST APPLIED IN DGHS PRE-QUALIFICATION 2022-23 FY) Reason of Not Pre-Qualification 39 – Atracuriam Inj. 10mg/ml.(3ml) Expired GMP Certificate 49 - Bupivacaine Spinal 2ml Inj. Expired GMP Certificate 100 – Diclofenac Sodium 50mg Tab Expired GMP Certificate + Said Item declared Substandard over 5% against supplied stock to Public Sector 130 – Glycopyrrolate + Neostigmine Inj. (0.5mg / 2.5mg) Expired GMP Certificate 181 – Midazolam Inj. 1mg/ml (5ml) Expired GMP Certificate 188 – Nalbuphine Inj. 10mg (1ml) Expired GMP Certificate 226 – Povidone – Iodine 7.5% Scrub (450ml) Expired GMP Certificate + DRAP Approval of Quoted Pack not attached 227 – Povidone – Iodine 10% Solution (450ml) Expired GMP Certificate + DRAP Approval of Quoted Pack not attached In above regard, we are enclosing the applied letter for Renewal of GMP Certificate dated 25th March 2022, its Challan dated 29th April 2022, Valid GMP Certificate having expiry date of 1st July 2024, along with Audit Inspection Report (2022), for onward submission in the grievance response. 2ndly, regarding the objection of "DRAP APPROVAL OF QUOTED ITEM NOT ATTACHED" against Item / Inq. no. 226 (Povidone – Iodine Scrub 7.5%, 450ml) and Item / Inq. no. 227 (Povidone – Iodine Solution 10%, 450ml). In that concern, we would like to inform you that we have submitted the Circular from PPMA (Circular no. 140/94, dated 3rd October 1994) addressing to all Heads of Member Companies regarding the Uniformity in Packs Size of Liquid Preparation either in 60ml, 120ml & 450ml Pack Size, as instructed by Ministry of Health (Letter no. F.3-2/94-Reg-II, dated 22nd August 1994). The Registration date of Pyodine Solution is 29 Oct 1988 & Registration date of Pyodine Scrub is 27 Feb 1990 in Ministry of Health, Govt. of Pakistan. After receiving above mentioned Circular from PPMA, Brookes Pharma had complied on prior basis as per the instruction from Ministry of Health. So, in that way, we are submitting the more documents to show the Quoted Pack Size Volume of Pyodine Scrub 450ml	Mr. Shahid Hameed, Sales Manager from M/s Brookes Pharma Private Limited. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
176	49	Bupivacaine (hydrochloride) (spinal) Injection 0.75% (Amp of 2 ml)	Brookes Pharma Private Limited.	Sensocain Spinal Injection	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.	attached In above regard, we are enclosing the applied letter for Renewal of GMP Certificate dated 25th March 2022, its Challan dated 29th April 2022, Valid GMP Certificate having expiry date of 1st July 2024, along with Audit Inspection Report (2022), for onward submission in the grievance response. 2ndly, regarding the objection of "DRAP APPROVAL OF QUOTED ITEM NOT ATTACHED" against Item / Inq. no. 226 (Povidone – Iodine Scrub 7.5%, 450ml) and Item / Inq. no. 227 (Povidone – Iodine Solution 10%, 450ml). In that concern, we would like to inform you that we have submitted the Circular from PPMA (Circular no. 140/94, dated 3rd October 1994) addressing to all Heads of Member Companies regarding the Uniformity in Packs Size of Liquid Preparation either in 60ml, 120ml & 450ml Pack Size, as instructed by Ministry of Health (Letter no. F.3-2/94-Reg-II, dated 22nd August 1994). The Registration date of Pyodine Solution is 29 Oct 1988 & Registration date of Pyodine Scrub is 27 Feb 1990 in Ministry of Health, Govt. of Pakistan. After receiving above mentioned Circular from PPMA, Brookes Pharma had complied on prior basis as per the instruction from Ministry of Health. So, in that way, we are submitting the more documents to show the Quoted Pack Size Volume of Pyodine Scrub 450ml	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
177	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Brookes Pharma Private Limited.	Arnil Tablet	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	The firm did not contest for the quoted item.	
178	130	Glycopyrrolate +Neostigmine Injection 0.5 mg/ml injection	Brookes Pharma Private Limited.	Neo-Pyrolate Injection	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
179	181	Midazolam Injection 1mg/ml	Brookes Pharma Private Limited.	Hypo zam Injection	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.	(against Item / Inq. no. 226 - Povidone – Iodine Scrub 7.5%, 450ml) and Pyodine Solution 450ml (against Item / Inq. no. 227 (Povidone – Iodine Solution 10%, 450ml). List of Submitting Documents for Inq. No. 226 (Povidone-Iodine Scrub 7.5%) is mentioned below: • Drug Registration Certificate of Pyodine Scrub • Circular from PPMA (Circular no. 140/94, dated 3rd October 1994) • Ministry of Health (Letter no. F.3-2/94-Reg-II, dated 22nd August 1994) • Price Re-Fixation Letter from Ministry of Health [F.11-4/2009 – DDC (P) (8th PAC), dated 11th September 2009] • S.R.O from DRAP [No. 328 (I)/2012] • Price Re-Fixation Letter from DRAP [F.11-11/2012 – DDC (P) (DRAP), dated 7th Feb 2013] List of Submitting Documents for Inq. No. 227 (Povidone-Iodine Solution 10%) is mentioned below: • Drug Registration Certificate of Pyodine Solution • Circular from PPMA (Circular no. 140/94, dated 3rd October 1994) • Ministry of Health (Letter no. F.3-2/94-Reg-II, dated 22nd August 1994) • S.R.O for Price Increase from Ministry of Health [F.9-21/95, dated 26th June 1995], along with our letter. • Price Fixation Letter from Ministry of Health [F.9-22/2000 – Price (Vol-III), dated 3rd Jan 2000] along with our response letter. • Notification from Ministry of Health [SRO no. 4 (I)/2000, dated 2nd Jan 2001] • Price Re-Fixation Letter from Ministry of Health [F.11-3/2007 – DDC (P), dated 31st May 2007] • Price Re-Fixation Letter from Ministry of Health [F.11-4/2009 – DDC (P) (8th PAC), dated 11th September 2009] • S.R.O from DRAP [No. 328 (I)/2012] • Price Re-Fixation Letter from DRAP [F.11-11/2012 – DDC (P) (DRAP), dated 7th Feb 2013]	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
180	188	Nalbuphine Hcl Injection 10mg/ml	Brookes Pharma Private Limited.	Sonotic Injection	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.	
181	226	Povidone – iodine Scrub 7.5%	Brookes Pharma Private Limited.	Pyodine Scrub	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 1: Quoted item section on GMP not prequalified due to expired certificate. Clause No. 2: DRAP approval of quoted pack not attached.	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause No. 2: The firm provided DRAP approval of 450ml Pack, which was accepted.	
182	227	Povidone – iodine Solution 10%	Brookes Pharma Private Limited.	Pyodine Solution	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 1: Quoted item section on GMP not prequalified due to expired certificate. Clause No. 2: DRAP approval of quoted pack not attached.	<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause No. 2: The firm provided DRAP approval of 450ml Pack, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
183	81	Clarithromycin Suspension 125mg/5ml	CCL Pharmaceuticals Pvt Ltd.	NEO-KLAR	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>	<p>With reference to your Technical Evaluation Report of Pre-qualification for the year 2022-23. According to said report our firm and all offered products declared not Pre-qualified due to GMP, EHS Policy (ISO-45001) and SOPs Product Recall. In this regard, following documents are attached for your kind consideration. 1). Drug Regulatory Authority of Pakistan (DRAP) Letter regarding validity of GMP, Renewal Application & Fee Paid Challan of GMP and GMP Certificate. 2). Valid Health Safety & Environmental Policy WITH SOP's. 3). Valid Product Recall SOP's. You are requested to kindly accept our Grievance and declare our firm & all our offered products as Pre-Qualified for procurement of quality medicines at economical price.</p>	<p>Mr. Rashid Munir, Institutional Sales Manager from M/s CCL Pharmaceuticals Pvt Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
184	82	Clarithromycin Tablets 500mg	CCL Pharmaceuticals Pvt Ltd.	NEO-KLAR	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>	<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
185	85	Clopidogrel Tablets 75 mg	CCL Pharmaceutical s Pvt Ltd.	Noclot	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.
186	114	Enticavir 0.5mg tab	CCL Pharmaceutical s Pvt Ltd.	TACAVIR	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.
187	118	Escitalopram Tablets 10mg	CCL Pharmaceutical s Pvt Ltd.	EXAPRO	Not Qualified	<u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
188	126	Glimepiride Tablets 2mg	CCL Pharmaceuticals Pvt Ltd.	ORINASE	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
189	154	Levofloxacin Tablet 250mg	CCL Pharmaceuticals Pvt Ltd.	LEVOCIL	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
190	173	Metoclopramide (hydrochloride) Injection 10mg	CCL Pharmaceuticals Pvt Ltd.	METOMID E	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
191	174	Metoclopramide (hydrochloride) Syrup 5mg/5ml	CCL Pharmaceuticals Pvt Ltd.	METOMID E	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
192	185	Montelukast Tablets 10 mg	CCL Pharmaceuticals Pvt Ltd.	MONTAIR	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
193	249	Sitagliptin 50mg Tablet	CCL Pharmaceuticals Pvt Ltd.	Sita Tablet	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
194	263	Tenofovir (disoproxil fumarate) 300 mg	CCL Pharmaceuticals Pvt Ltd.	TENO VIR	Not Qualified	<p><u>Firmwise</u> Clause No.03: GMP Certificate Expired. Clause no 06: Valid ISO 45001 not provided. Clause no 18: Review of drug recall SOP is past its due date.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no 06: The firm provided ISO 18001/45001 (EHS) Policy implementation SOPs, which was accepted. Clause no 18: The firm provided revised drug recall SOP, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP not prequalified due to expired certificates.</p>
195	146	Ipratropium Bromide Nebulizing Solution	Chiesi pharmaceuticals Private limited	Atem (0.025% Nebuliser Solution)	Not Qualified	<p><u>Firmwise</u> Clause no. 4: Valid COPP Containing quoted strength not attached.</p> <p><u>Itemwise</u> Clause no. 1: valid DRC containing quoted strength not provided. Clause no. 3: Quality compliance standards (EMA/JMHLW/USFDA/WHO) not attached.</p>	<p>we do hereby submit our response as follows; 1. Clause No:1: Valid DRC containing quoted strength is not attached. Please note that product strength is 0.5mg/2mL which is equivalent to 0.25mg/1mL or 0.025%. On DRC, strength is mentioned as 0.5mg/2mL which is equivalent to 0.025%. 2. Clause No 3: Quality Compliance Standards. Please note that our product complies EMA standards for quality. Please find here attached EMA Approval. 3. Clause No.4: Valid CoPP containing quoted strength not attached. Please note that product strength is 0.5mg/2mL which is equivalent to 0.25mg/1mL or 0.025%. On CoPP, per vial strength is mentioned i-e, 0.50mg/2mL which is equivalent to 0.25/1mL or 0.025%. We humbly request to please consider the strengths are equivalent (0.5mg/2mL/0.25mg/1mL/0.025%) In view of facts narrated here above, we humbly request your good self to please not to disqualify us as quoted strength is the same and equivalent to as reported on CPP and Drug Registration Letter i-e, 0.5mg/2ml/0.025mg/1mL/0.025%.</p>	<p>Mr. Zahid Mafeem, Tender Services Manager from M/s Chiesi pharmaceuticals Private limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u> Clause no. 4: The firm provided valid COPP Containing quoted strength; hence, grievance of the firm was accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 1: The firm provided valid DRC containing quoted strength; hence, grievance of the firm was accepted to the extent of this parameter. Clause no. 3: The firm provided Quality compliance standard (EMA); hence, grievance of the firm was accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
196	16	Amlodipine Tablets 5 mg	CITI PHARMA	Modopine	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.	we are humbly submitting our grievance for the removal of those objections as follows. Objection: ' Firmwise: Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.' REPLY: It is humbly stated that make, model and manufacturer name are mentioned in the calibration record. We are hereby re-submitting the calibration record (calibrated by Instruemends) along with a letter from the manufacturer (Instruemends) of stability chambers certifying the model of the stability chambers. Objection: ' Itemwise: Clause no.2: Valid DRC (renewal) not attached. Item no. 199. Omeprazole Capsule 20mg.' REPLY: It is respectfully submitted that DRAP issued DRC of Item no. 199. Omeprazole Capsule 20mg under change of title from Askri Pharma to CITI Pharma and pellet source approval on dated 28th, Aug-2017 (letter attached) as approved in 271st meeting of registration board. it is humbly stated that renewal of said item is not due till date and valid upto 28th, Aug-2022.	Mst. Khansa Rustom, Head of Quality from M/s CITI Pharma attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
197	41	Azithromycin Capsules/Tab 250mg	CITI PHARMA	Zyask 250mg Capsules	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no 3: Experience of quoted item of manufacturer from date of registration is less than one year.		The firm did not contest for the quoted item.
198	43	Azithromycin Susp 200mg/5ml	CITI PHARMA	zyask dry powder suspension	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no 3: Experience of quoted item of manufacturer from date of registration is less than one year.		The firm did not contest for the quoted item.
199	57	Cefixime Capsule/Tablets 400mg	CITI PHARMA	cefask capsule 400mg	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
200	58	Cefixime Suspension 100mg/5ml	CITI PHARMA	Cefask Dry Suspension	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
201	68	Cetirizine Tablets 10mg	CITI PHARMA	Avazin	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
202	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	CITI PHARMA	Floxcip	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
203	85	Clopidogrel Tablets 75 mg	CITI PHARMA	Clopeg	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
204	120	Fluconazole Capsules 150mg	CITI PHARMA	Flucogals Capsules	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no 3: Experience of quoted item of manufacturer from date of registration is less than one year.		The firm did not contest for the quoted item.
205	126	Glimepiride Tablets 2mg	CITI PHARMA	DIAGLIM	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
206	154	Levofloxacin Tablet 250mg	CITI PHARMA	Lenon	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
207	160	Losartan Potassium Tablet 50mg	CITI PHARMA	Lopec 50mg	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
208	167	Mefenamic acid Tablet 500 mg	CITI PHARMA	Ponfab	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
209	178	Metronidazole Tablets 200 mg	CITI PHARMA	Asknid 200mg Tablet	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no 3: Experience of quoted item of manufacturer from date of registration is less than one year.		The firm did not contest for the quoted item.
210	179	Metronidazole Tablets 400 mg	CITI PHARMA	Asknid 400mg Tablet	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no 3: Experience of quoted item of manufacturer from date of registration is less than one year.		The firm did not contest for the quoted item.
211	185	Montelukast Tablets 10 mg	CITI PHARMA	Cingol	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.
212	199	Omeprazole Capsule 20mg	CITI PHARMA	Promy	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record. <u>Itemwise</u> Clause no.2: valid DRC(renewal) not attached.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted. Clause no.2: The firm provided valid DRC of the quoted item, which was accepted.
213	209	Paracetamol Tablet 500 mg	CITI PHARMA	Askprol	Not Qualified	<u>Firmwise</u> Clause No. 12: Brand and Model no. of Stability Chambers not mentioned on calibration record.		<u>Firmwise</u> Clause No. 12: The firm provided calibration certificates of stability chambers with Make and Model no. mentioned, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
219	138	Ibuprofen Susp. 100mg/5ml	Don Valley Pharmaceuticals (Pvt.) Ltd.	Ibtol 100mg/5ml	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	shows that percentage of Substandard samples of quoted items is less than 5%. Objection: ' Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Item No. 138 Ibuprofen Susp. 100mg/5ml 90ml REPLY: Detail of Batches of Ibtol Suspension 100mg/5ml (90ml) from 01-01-2021 to 23-06-2022 is attached in Given Annexure. Report shows that percentage of Substandard samples of quoted items is less than 5%. Objection: ' Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Item No. 199	<u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 139 batches were manufactured out of which 4 were declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
220	138	Ibuprofen Susp. 100mg/5ml	Don Valley Pharmaceuticals (Pvt.) Ltd.	Ibtol 100mg/5ml	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	Omeprazole Capsule 20mg 14's REPLY: Detail of Batches of Opicap 20mg Caps (14's) from 01-01-2021 to 23-06-2022 is attached in Given Annexure. Report shows that percentage of Substandard samples of quoted items is less than 5%. Objection: ' Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Item No. 199	<u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 139 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
221	199	Omeprazole Capsule 20mg	Don Valley Pharmaceuticals (Pvt.) Ltd.	Opicap 20mg Caps.	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	Omeprazole Capsule 20mg 100's REPLY: Detail of Batches of Opicap 20mg Caps (100's) from 01-01-2021 to 23-06-2022 is attached in Given Annexure. Report shows that percentage of Substandard samples of quoted items is less than 5%.	<u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 56 batches were manufactured out of which 4 were declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
222	199	Omeprazole Capsule 20mg	Don Valley Pharmaceuticals (Pvt.) Ltd.	Opicap 20mg Caps.	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 56 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
223	26	Amoxicillin Injection 500mg	English Pharmaceutical Industries	Enmox 500mg Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>	<p>our firm was not prequalified because of following reasons. 1. Firm wise : Clause No. 2 GMP certificate Expire (See Annexure-I) Clause No. 19 Form 29 by SECP / Form C not attached (See Annexure-I) 2. Item wise: Quoted item section on GMP not prequalified due to expired Certificate (See Annexure-II) It is requested to kindly consider the documents provided by firm with this letter and prequalified our firm so that we can serve our people.</p>	<p>Mr. Aitzaz Shirazi, Distributor from M/s English Pharmaceutical Industries attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
224	65	Cephadrine Injection 500mg	English Pharmaceutical Industries	Enceph 500mg injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
225	114	Enticavir 0.5mg tab	English Pharmaceutical Industries	Bcavir 0.5mg Tablet	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
226	148	Iron Sucrose Injection 100mg/5ml	English Pharmaceutical Industries	Enofer injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
227	200	Omeprazole Injection 40mg	English Pharmaceutical Industries	Zolat 40mg injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
228	261	Tazobactum+Piperacillin Injection 500mg+4gm	English Pharmaceutical Industries	Hicin 4.5g Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
229	279	Vitamin D3 Injection 5mg	English Pharmaceutical Industries	Vitaferol Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
230	280	Vitamin K1 2mg/ml Injection	English Pharmaceutical Industries	VIT K1 Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 3: GMP certificate expired. Clause no. 19: form 29 by SECP/Form C not attached.</p> <p><u>Itemwise</u> Clause no. 1: Quoted item section on GMP not prequalified due to expired certificate.</p>		<p><u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. Clause no. 19: The firm provided Form C, which was accepted.</p> <p><u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.</p>
231	282	Water for injection 5 ml Sterile	FYNK Pharmaceuticals	Water for Injection	Not Qualified	<p><u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>	<p>Our firm has not been prequalified for said product on the basis of the declaration of more than 5% substandard batches by DTLs. In this regard we are hereby submitting the facts about the matter for your kind consideration: 1. From Jan 2021 to Jun 2022 M/s Fynk Pharmaceuticals produced 123 batches of Water for Injection. Out of which 08 batches bearing Batch No: WI-544, WI-659, WI-678, WI-679, WI-680, WI-605, WI-621 & WI-627 were supplied to Govt. Institutions and the remaining were supplied in the commercial market. 2. Out of the total 08 batches which were supplied to Govt. Sector, only one Batch No: WI-621 was declared failed by DTL, Lahore. So the percentage of failed batches (01 out of total 123 batches) would be as under: $1/123 \times 100 = 0.813\%$ Which is very much less than the maximum benchmark percentage i.e. 5 % set for prequalification and beyond this, it would not be acceptable. As we already explained above that our DTL fail percentage is within the acceptable limit of 5% and further it is very much less than 5% i.e. only 0.813 % out of the total produced and supplied 123 batches. We are herewith attaching the batch production record with Q.C references as well as DTL reports of all the concerned batches as a ready reference for your kind perusal.</p>	<p>Mr. Maqsood Ahmed, Institutional Sales Manager from M/s FYNK Pharmaceuticals attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that:</p> <p><u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 123 batches were manufactured out of which 2 were declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
232	254	Streptokinase Powder for injection 1.5 million IU	Gene-Tech Laboratories	DICLAIR-ST	Not Qualified	<u>Firmwise</u> Clause no. 14: Minimum annual financial turnover less than Rs. 330 million	we are requesting you to please Re-Consider our rejected Pre-Qualification case due to following facts/justifications: 1. WE, M/s Gene-Tech Laboratories, are importer and sole agent of inj. Diclair ST 1.5 miu (Streptokinase) that is manufactured by BBT, Germany. 2. Gene-Tech Laboratories is medium size biotech marketing companies that are marketing lifesaving medicines by importing them from different countries. Due to our limited and focused business our turnover is less than Rs. 300 million during fiscal year. 3. Inj. Streptokinase is lifesaving medicine and used in the treatment of Life threatening Acute Myocardial Infarction. This product has been used only in third world countries and has limited supplies and productions. 4. Gene-Tech Laboratories is supplying inj. Diclair ST in all major hospitals of Punjab since the last 12 years and Alhamdulillah there is not a single complaint of short supply or any other complaint. 5. Inj. Diclair ST (Streptokinase) has both Raw material and Finished Product from Germany and has European Quality Certificate. Dear Sir, Highly appreciating it for your consideration to avoid the shortage of above necessary and lifesaving medicine and re-consider our Pre-Qualification Application for year2021-2022.	Mr. Muhammad Noman Ahmad, Distributor of M/s Gene-Tech Laboratories attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 330 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.
233	118	Escitalopram Tablets 10mg	Genix Pharma Pvt. Ltd.	Depsit	Not Qualified	<u>Itemwise</u> Clause no 2: DRAP approval of quoted pack not attached.	We Genix Pharma Pvt. Ltd, participated in DGHS pre-qualification of Drugs / Medicines for FY 2022-23. We are declared Non-responsive against quoted item No: 281 (Water for Injection 10ml) due to the sample substandard over 5%. Attached please find the BMR of WFI from 01/01/2021. For your satisfaction we are	The firm did not contest for the quoted item.
234	147	Iron iii Hydroxide Polymaltose Syrup	Genix Pharma Pvt. Ltd.	RBC	Not Qualified	<u>Itemwise</u> Clause no 2: DRAP approval of quoted pack not attached.		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
235	281	Water for injection 10 ml Sterile	Genix Pharma Pvt. Ltd.	Water For Injection	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	submitting the BMR of WFI to re-evaluate our product and request you to declare us as responsive from to create healthy competition between bidders Favorable response requested.	Mr. Imran Bashir Bhutta, Business Manager from M/s Genix Pharma Pvt. Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 6: The firm could not justify its claim that Samples Substandard of quoted item (less than 5%) from (01-01-2021); hence, grievance of the firm was not accepted to the extent of this parameter.
236	18	Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets	Getz Pharma (Pvt) Limited	AMCLAV TAB 1GM TP 6'S (CSH)	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not attached. <u>Itemwise</u> Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.	Refer to your Pre-qualification evaluation Report dated July 1,2022 our Grievances on our clauses is mentioned Below: - FIRM WISE GRIEVANCES □ Clause no. 06: Firm did not attach FBR tax returns of calendar year 2020. Grievance: - FBR documents clause is S. No. 14. Our products which are lying at serial No # 18 23 24 25 38 41 42 43 44 57 58 59 60 61 62 64 77 80 81 82 90 118 126 143 144 145 148 152 154 170 184 185 199 200 241 242 249 252 263 269 279 281 are not pre-qualified and the remarks is "Firm did not attach FBR tax returns of calendar year 2020". Getz Pharma is the largest Pharmaceutical Company in Pakistan and having financial turnover of more than 40 billion, which is higher than the Pre-Qualification requirement for any single financial year as evidence by tax documents submitted for the tax year 2018, 2019 & 2020. For further satisfaction of Grievances Committee, we are also submitting FBR Income tax return for the tax year 2021 (Calendar year 2020) Copy Attached. Please refer Annexure-A □ Clause no. 17: Undertaking "None of its supplied	Mr. Sadaan Azhar, Area Sales Manager from M/s Getz Pharma (Pvt) Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted. <u>Itemwise</u> Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
237	23	Amoxicillin + Clavulanic Acid Suspension 125 mg + 31.25 mg / 5 ml	Getz Pharma (Pvt) Limited	AMCLAV SUSP 156.25MG/ 5ML TP 1'S (CSH)	Not Qualified	<p>Firmwise</p> <p>Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p> <p>Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not attached.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.</p>	<p>batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not attached. Grievance: - Our Product's Lying at Serial No # 18, 23, 24, 25, manufactured by TPM M/s. CSH Pharmaceutical & Serial No # 57, 58, 59 manufactured by our Third-Party Manufacturing M/s. Opal Laboratories are not Qualified. As products are registered in the name of Getz Pharma, we (Getz Pharma) have already submitted notarized undertaking with prequalification documents that's none of supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission. Copy Attached for your Reference. Please refer Annexure-B</p> <p>□ Clause no. 15: Building Fitness Certificate/ approved Layout plan is not attached. Grievance: -</p>	<p><u>Firmwise</u></p> <p>Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p> <p>Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.</p>
238	24	Amoxicillin + Clavulanic Acid Suspension 250mg+62.5mg/5ml	Getz Pharma (Pvt) Limited	AMCLAV DS SUSP 312.50MG/ 5ML TP 1'S (CSH)	Not Qualified	<p>Firmwise</p> <p>Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p> <p>Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not attached.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.</p>	<p>We have already submitted DRAP Approved Layout Plan (Copy Attached). Please refer Annexure-C</p> <p>□ Clause no 2: The Firm did not provide valid Drug Registration Certificates of the quoted item.</p> <p>Grievance: - Our Quoted Products which are lying at Serial # 18, 23, 24, 25, 57, 58, 59, 60, 61, 62, 152, 269, 279 are not qualified that we have not provided Valid Drug Registration Certificates of the quoted items. We have already submitted Valid DRC of the above quoted products with prequalification documents. However, we are attaching again for your kind reference. (Copy Attached). Please refer Annexure-D The Product which is lying at PQ Inq# 44. We are manufacturing this product locally in Pakistan with DRAP registration number 081539. Mistakenly incorrect registration number written on online portal due to typographical error. However, we have submitted DRC with registration number 081539 on</p>	<p><u>Firmwise</u></p> <p>Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p> <p>Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
239	25	Amoxicillin + Clavulanic Acid Tablets 625 mg	Getz Pharma (Pvt) Limited	AMCLAV TAB 625MG TP 6'S (CSH)	Not Qualified	<p><u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not attached.</p> <p><u>Itemwise</u> Clause 2 & 3: The firm did not provide valid DRC of the quoted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.</p>	<p>submitted DRC with registration number 001599 on online portal and hard copy as well. We are again attaching DRC for your kind reference. Please refer Annexure-E □ Clause no 3: - The Quoted Item Does Not Have at Least One-Year Experience of Manufacturer from Date of Registration. Grievance: - P.Q Inq# 18, 23, 24, 25, 57, 58, 59, 60, 61, 62, 152, not qualified. We have attached the Drug registration Certificates along with Valid renewals in Pre-Qualification Documents & as per DRC's there is clearly mentioned date of registration is more than one year of our all-quoted products Hence, it means our quoted products are more than one year experience. (Copy Attached). Please refer Annexure-D The Products which are lying at P.Q In# 38, 43, 81, 126, 154, 199. We, Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25, Korangi Industrial Area (Unit-1), Karachi, hereby inform your good office that we have received the registration of following products from PE&R Division of DRAP as change in registration status of products from one DML to another DML without any change in name / title of registration holder / manufacturer and management. Further, DRAP has granted the same Registration Nos. to all the products that were issued earlier to products manufactured at Getz Pharma (Pvt.) Limited situated at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Hence all the mentioned products have more than one year experience from date of Registration. We are again attaching the DRC of the product for kind reference. Please refer Annexure-F □ Clause no 6: - Samples Substandard of Quoted item (over 5%) from (01-01-2021). Grievance: PQ Inq# 64 not qualified. We produced 24 batches of Lenwin Cap 500mg from Jan-2021 to till date and only Batch No. 1539 (Manufactured by M/s. Novamed)</p>	<p><u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted.</p> <p><u>Itemwise</u> Clause 2 & 3: The firm provided valid DRC of quoted item, which was accepted.</p>
240	38	Atorvastatin Tablets 20mg	Getz Pharma (Pvt) Limited	LIPIGET TAB 20MG TP 10'S (SEPACK)	Not Qualified	<p><u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p> <p><u>Itemwise</u> Clause no. 03: The quoted item does not have at least One-year experience of manufacturer from date of registration.</p>	<p>that we have received the registration of following products from PE&R Division of DRAP as change in registration status of products from one DML to another DML without any change in name / title of registration holder / manufacturer and management. Further, DRAP has granted the same Registration Nos. to all the products that were issued earlier to products manufactured at Getz Pharma (Pvt.) Limited situated at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Hence all the mentioned products have more than one year experience from date of Registration. We are again attaching the DRC of the product for kind reference. Please refer Annexure-F □ Clause no 6: - Samples Substandard of Quoted item (over 5%) from (01-01-2021). Grievance: PQ Inq# 64 not qualified. We produced 24 batches of Lenwin Cap 500mg from Jan-2021 to till date and only Batch No. 1539 (Manufactured by M/s. Novamed)</p>	<p><u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p> <p><u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.</p>
241	41	Azithromycin Capsules/Tab 250mg	Getz Pharma (Pvt) Limited	ZETRO CAPS 250MG TP 10'S CHG	Not Qualified	<p><u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p>	<p>that we have received the registration of following products from PE&R Division of DRAP as change in registration status of products from one DML to another DML without any change in name / title of registration holder / manufacturer and management. Further, DRAP has granted the same Registration Nos. to all the products that were issued earlier to products manufactured at Getz Pharma (Pvt.) Limited situated at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Hence all the mentioned products have more than one year experience from date of Registration. We are again attaching the DRC of the product for kind reference. Please refer Annexure-F □ Clause no 6: - Samples Substandard of Quoted item (over 5%) from (01-01-2021). Grievance: PQ Inq# 64 not qualified. We produced 24 batches of Lenwin Cap 500mg from Jan-2021 to till date and only Batch No. 1539 (Manufactured by M/s. Novamed)</p>	<p><u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p>
242	42	Azithromycin Capsules/Tab 500mg	Getz Pharma (Pvt) Limited	ZETRO TAB 500MG TP 6'S	Not Qualified	<p><u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p>	<p>that we have received the registration of following products from PE&R Division of DRAP as change in registration status of products from one DML to another DML without any change in name / title of registration holder / manufacturer and management. Further, DRAP has granted the same Registration Nos. to all the products that were issued earlier to products manufactured at Getz Pharma (Pvt.) Limited situated at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Hence all the mentioned products have more than one year experience from date of Registration. We are again attaching the DRC of the product for kind reference. Please refer Annexure-F □ Clause no 6: - Samples Substandard of Quoted item (over 5%) from (01-01-2021). Grievance: PQ Inq# 64 not qualified. We produced 24 batches of Lenwin Cap 500mg from Jan-2021 to till date and only Batch No. 1539 (Manufactured by M/s. Novamed)</p>	<p><u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
243	43	Azithromycin Susp 200mg/5ml	Getz Pharma (Pvt) Limited	ZETRO SUSP 15ML TP	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The qouted item does not have at least One-year experience of manufacturer from date of registration.	declared substandard by DTL Lahore which is less than 5% as per P.Q Clause No.6. However, M/s Novamed Pharma retested this product on retained samples of said batch after issuance of DTL report and all parameters including assay/dissolution/uniformity of dosage units were found within specifications and M/s Novamed Pharma requested to DTL Lahore for retesting this Batch from NIH Laboratory. We are attaching letter copy for your kind reference. Please refer annexure-G □ The	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.
244	44	Beclomethasone (Dipropionate) Inhaler 250 mcg	Getz Pharma (Pvt) Limited	BEKSON FORTE HFA 250MCG MDI TP 1'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> CLause no. 02: The DRN of qouted product on DRC is different from that of written on online application form.	Quoted item Water for injection 10 ml Sterile does not comply with the advertised specifications. Grievance: - PQ Inq# 281 not prequalified. We Getz Pharma have valid approval of WFI 10ml sterile with registration number 053043 and DRAP approved valid DRC already attached in online portal and with hard copy. However wrong brand name mistakenly mentioned against WFI 10ml. We are providing WFI as Free of Cost with the product and we assure you that same will be provided with approved prequalified product. We are again attaching product DRC with DRAP above letter copy for your kind reference. Please refer Annexure-H IMPORTED ITEM □ ITEM WISE	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> CLause no. 02: The firm provided valid DRC of quoted item, which was accepted.
245	57	Cefixime Capsule/Tablets 400mg	Getz Pharma (Pvt) Limited	CEFIGET CAPS 400MG TP 5'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Clause no. 15: Building Fitness Certificate/ approved Layout plan is not attached. Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not as prescribed in the PQ documents. <u>Itemwise</u> Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.	CLAUSE 3: - The Firm did not provide Quality Compliance Standards certificate of quoted product. Grievance: - Our Product lying at P.Q # 170 have European quality complies standard certificate and copy of certificate is attached with letter for your reference. Please refer Annexure-I	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. Clause no. 15: The firm provided Building fitness certificate, which was accepted. Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted. <u>Itemwise</u> Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
246	58	Cefixime Suspension 100mg/5ml	Getz Pharma (Pvt) Limited	CEFIGET SUSP 30ML TP	Not Qualified	<p>Firmwise</p> <p>Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p> <p>Clause no. 15: Building Fitness Certificate/ approved Layout plan is not attached.</p> <p>Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not as prescribed in the PQ documents.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.</p>		<p>Firmwise</p> <p>Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p> <p>Clause no. 15: The firm provided Building fitness certificate, which was accepted.</p> <p>Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.</p>
247	59	Cefixime Suspension 200mg/5ml	Getz Pharma (Pvt) Limited	CEFIGET DS SUSP 30ML TP	Not Qualified	<p>Firmwise</p> <p>Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.</p> <p>Clause no. 15: Building Fitness Certificate/ approved Layout plan is not attached.</p> <p>Clause no. 17: Undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission." is not as prescribed in the PQ documents.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.</p>		<p>Firmwise</p> <p>Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.</p> <p>Clause no. 15: The firm provided Building fitness certificate, which was accepted.</p> <p>Clause no. 17: The firm provided undertaking "None of its supplied batch in Public Sector Institutions has been declared Spurious & Adulterated since last 3 years till the closing date of Prequalification Document submission.", which was accepted.</p> <p>Itemwise</p> <p>Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
248	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Getz Pharma (Pvt) Limited	GETOFIN IV 1G TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Itemwise Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.
249	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Getz Pharma (Pvt) Limited	GETOFIN INJ IV 250MG TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Itemwise Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.
250	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Getz Pharma (Pvt) Limited	GETOFIN IV 500MG TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Itemwise Clause 2& 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause 2& 3: The firm provided valid DRC of quoted item, which was accepted.
251	64	Cephradine Capsule 500mg	Getz Pharma (Pvt) Limited	LENWIN CAPS 500MG TP 12'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 24 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
252	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Getz Pharma (Pvt) Limited	CIPESTA TAB 500MG TP 10'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
253	80	Ciprofloxacin Injection 200mg / 100ml	Getz Pharma (Pvt) Limited	CIPESTA IV 200MG/100 ML TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
254	81	Clarithromycin Suspension 125mg/5ml	Getz Pharma (Pvt) Limited	CLARITEK GRAN 60ML TP	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The qouted item does not have at least One-year experience of manufacturer from date of registration.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.
255	82	Clarithromycin Tablets 500mg	Getz Pharma (Pvt) Limited	CLARITEK TAB 500MG TP 10'S (NEW) CHG	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
256	90	Daclatasvir 60mg Tablet	Getz Pharma (Pvt) Limited	DACLAGE T TAB 60MG TP 28'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
257	118	Escitalopram Tablets 10mg	Getz Pharma (Pvt) Limited	ZAVGET TAB 10MG TP 14'S CHG	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
258	126	Glimepiride Tablets 2mg	Getz Pharma (Pvt) Limited	GETRYL TAB 2MG TP 20'S (SEPACK)	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The qouted item does not have at least One-year experience of manufacturer from date of registration.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.
259	143	Insulin comp 70/30 Injection 100 IU/ml	Getz Pharma (Pvt) Limited	INSUGET INJ 70/30 10ML TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
260	144	Insulin NPH Injection 100 IU/ml	Getz Pharma (Pvt) Limited	INSUGET INJ NPH 10ML TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
261	145	Insulin Regular Injection 100 IU/ml	Getz Pharma (Pvt) Limited	INSUGET INJ REGULAR 10ML TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
262	148	Iron Sucrose Injection 100mg/5ml	Getz Pharma (Pvt) Limited	FEROTEIN S INJ 100MG/5M L TP 5'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
263	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	Getz Pharma (Pvt) Limited	LILAC SYP 120ML TP 1'S	Not Qualified	Firmwise Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. Itemwise Clause 2 & 3: The firm did not provide valid DRC of the qouted item as per Clause 2 & 3 of the Itemwise Criteria of the PQ documents.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause 2 & 3: The firm provided valid DRC of quoted item, which was accepted.
264	154	Levofloxacin Tablet 250mg	Getz Pharma (Pvt) Limited	LEFLOX TAB 250MG TP 10'S (SEPACK) CHG	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The qouted item does not have at least One-year experience of manufacturer from date of registration.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.
265	170	Meropenem 1G Injection	Getz Pharma (Pvt) Limited	MEROGET IV 1G TP 1'S INCL 10MLx2 AMP	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The firm did not provide Quality Compliance Standards certificate of qouted product.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm did not provide Quality Compliance Standards certificates (EMA/JMHLW/US FDA/prequalified by WHO (Certificate) of qouted product; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
266	184	Montelukast 4mg Dry Powder sachet	Getz Pharma (Pvt) Limited	MONTIGET GRAN 4MG TP 14'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
267	185	Montelukast Tablets 10 mg	Getz Pharma (Pvt) Limited	MONTIGET TAB 10MG TP 14'S (NEW)	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
268	199	Omeprazole Capsule 20mg	Getz Pharma (Pvt) Limited	RISEK CAPS 20MG TP 14'S (SEPACK)	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 03: The quoted item does not have at least One-year experience of manufacturer from date of registration.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 03: The firm provided valid DRC of quoted item, which was accepted.	
269	200	Omeprazole Injection 40mg	Getz Pharma (Pvt) Limited	RISEK IV 40MG TP 1'S (REV)	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
270	241	Salbutamol (Sulfate) 100 micrograms and beclomethasone 50mcg inhaler	Getz Pharma (Pvt) Limited	XALTIDE HFA INHALER 100MCG+50MCG TP 1'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
271	242	Salbutamol (Sulfate) Inhaler 100 micrograms	Getz Pharma (Pvt) Limited	SALBO HFA 100MCG MDI TP 1'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
272	249	Sitagliptin 50mg Tablet	Getz Pharma (Pvt) Limited	TREVIA TAB 50MG TP 14'S CHG	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	
273	252	Sofosbuvir 400mg Capsule/Tablet	Getz Pharma (Pvt) Limited	SOFIGET TAB 400MG TP 28'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.	<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
274	263	Tenofovir (disoproxil fumarate) 300 mg	Getz Pharma (Pvt) Limited	TENOFO-B TAB 300MG TP (BOTL) 30'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted.
275	269	Tramadol HCl Injection 100mg/2ml	Getz Pharma (Pvt) Limited	PANTRA INJ 100MG TP 5'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 02: DRAP approval of qouted pack size is not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 02: The firm provided DRAP approval of 5's Pack, which was accepted.
276	279	Vitamin D3 Injection 5mg	Getz Pharma (Pvt) Limited	MIURA-D INJ 5MG/ML TP 1'S	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> Clause no. 02: DRAP approval of qouted pack size is not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 02: The firm provided DRAP approval of 1's Pack, which was accepted.
277	281	Water for injection 10 ml Sterile	Getz Pharma (Pvt) Limited	SODIUM CHLORIDE 0.9%W/V SOLUTION 10ML	Not Qualified	<u>Firmwise</u> Clause no. 06: The firm did not attach FBR tax returns of Calender year 2020. <u>Itemwise</u> The qouted item does not comply with the advertised specifications.		<u>Firmwise</u> Clause no. 14: The firm provided FBR tax returns of Calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 02: The provided DRC of qouted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
278	6	Albendazole Susp. 200mg / 5ml	GlaxoSmithKline Pakistan Limited	ZENTEL SUSPENSION 4%	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	We would like to inform you that we applied 43 items – Drugs / Medicines for pre-qualification with the Director General Health Services (DGHS), Punjab, Lahore for the year, 2022-23. We have been astonished to note through the Pre-qualification Evaluation Report uploaded by the DGHS, Punjab, Lahore that our all the items have not been qualified on the basis of some non-substantial observations. We are enclosing documents required against relevant product: Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of Short-falls GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E, Karachi (Manufacturing Site) 6 Albendazole Susp. 200mg / 5ml ZENTEL SUSPENSION 4% 200mg /5ml 10ml Clause no. 14: FBR Tax return of tax year 2021 not attached Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01.01.2021) It is pointed out here that clause 6 of knock down criteria stated as “samples Substandard of quoted item (Not over 5%) from (01-01-2021) if any.” Our tested sample have not been declared substandard over 5 % from 01-01-2021. Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	Mr. Nasir Mehmood, Key Account Manager from M/s GlaxoSmithKline Pakistan Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 116 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
279	7	Albendazole Tablets 200mg	GlaxoSmithKline Pakistan Limited	ZENTEL TABLET 200mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	clause 6 of knock down criteria stated as “samples Substandard of quoted item (Not over 5%) from (01-01-2021) if any.” Our tested sample have not been declared substandard over 5 % from 01-01-2021. Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
280	8	Allopurinol Tablet 300mg	GlaxoSmithKline Pakistan Limited	ZYLORIC TABLET 300mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
281	18	Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets	GlaxoSmithKline Pakistan Limited	AUGMENTIN BD 1000MG TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
282	19	Amoxicillin (trihydrate) Capsules/tablets 250mg	GlaxoSmithKline Pakistan Limited	AMOXIL CAPSULE S 250mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
283	20	Amoxicillin (trihydrate) Capsules/tablets 500 mg	GlaxoSmithKline Pakistan Limited	AMOXIL CAPSULE S 500mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 7 Albendazole Tablets 200mg ZENTEL TABLET 200mg 2’s Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 8 Allopurinol Tablet 300mg ZYLORIC TABLET 300mg 30’s 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets AUGMENTIN BD 1000MG (875mg+125mg) TABLETS 6’s 19 Amoxicillin (trihydrate) Capsules/tablets 250mg AMOXIL CAPSULE S 250mg 100’s Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
292	58	Cefixime Suspension 100mg/5ml	GlaxoSmithKline Pakistan Limited	FIXVAL SUSP 100MG/5ML	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 175 Metoclopramide (hydrochloride) Tablets 10mg MAXOLON Tablets 10mg 100's 208 Paracetamol Syrup/Susp 160mg /5ml or less. CALPOL PAEDIATRIC 120mg/5ml SUSPENSION Bottle of 100ml 1's Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of Short-falls	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
293	59	Cefixime Suspension 200mg/5ml	GlaxoSmithKline Pakistan Limited	FIXVAL SUSP 200MG/5ML	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E, Karachi (Manufacturing Site) 209 Paracetamol Tablet 500 mg CALPOL TABLETS 500MG 200's Firmwise	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
294	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	GlaxoSmithKline Pakistan Limited	TRAXON INJECTION IV 1gm	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 245 Salbutamol Syrup VENTOLIN SYRUP 2mg/5ml Bottle of 120ml 1's 256 Sulfamethoxazole + trimethoprim D/S Susp 400mg + 80mg/5ml SEPTRAN DS (400mg + 80mg/5ml) SUSPENSION Pack of 50ml 1's 257 Sulfamethoxazole + Trimethoprim D/S Tablets 800mg+160mg SEPTRAN DS (800mg + 160mg) TABLETS Tablet 100's GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (Manufacturing Site) 47 Betamethasone Cream 0.1% BETNOVATE 0.1% W/W CREAM Tube of 20gm 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
295	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	GlaxoSmithKline Pakistan Limited	TRAXON INJECTION IV 250MG	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 245 Salbutamol Syrup VENTOLIN SYRUP 2mg/5ml Bottle of 120ml 1's 256 Sulfamethoxazole + trimethoprim D/S Susp 400mg + 80mg/5ml SEPTRAN DS (400mg + 80mg/5ml) SUSPENSION Pack of 50ml 1's 257 Sulfamethoxazole + Trimethoprim D/S Tablets 800mg+160mg SEPTRAN DS (800mg + 160mg) TABLETS Tablet 100's GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (Manufacturing Site) 47 Betamethasone Cream 0.1% BETNOVATE 0.1% W/W CREAM Tube of 20gm 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
296	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	GlaxoSmithKline Pakistan Limited	TRAXON INJECTION IV 500MG	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 83 Clobetasol Cream/ointment 0.05% w/w DERMOVATE CREAM 0.05% w/w Tube of 20gm 1's 86 Clotrimazole Skin cream 1% w/w STIEMAZOL CREAM 1% w/w Tube of 10gm 1's 119 Ferrous salt + Folic Acid Capsule/Tablets FEFOL SPANSULE CAPSULE (150mg+0.5mg) 56's 214 Permethrin Lotion 5% Lotrix Lotion 5%w/w Bottle of 60ml 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
297	63	Cefurexime (Sodium) Injection 750mg	GlaxoSmithKline Pakistan Limited	Zinacef Injection 750mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no. 02: DRAP approval of quoted pack size is not attached.	Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 83 Clobetasol Cream/ointment 0.05% w/w DERMOVATE CREAM 0.05% w/w Tube of 20gm 1's 86 Clotrimazole Skin cream 1% w/w STIEMAZOL CREAM 1% w/w Tube of 10gm 1's 119 Ferrous salt + Folic Acid Capsule/Tablets FEFOL SPANSULE CAPSULE (150mg+0.5mg) 56's 214 Permethrin Lotion 5% Lotrix Lotion 5%w/w Bottle of 60ml 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 02: The firm provided DRAP approval of 1's Pack, which was accepted.
298	64	Cephradine Capsule 500mg	GlaxoSmithKline Pakistan Limited	VELOSEF CAPS 500MG	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 83 Clobetasol Cream/ointment 0.05% w/w DERMOVATE CREAM 0.05% w/w Tube of 20gm 1's 86 Clotrimazole Skin cream 1% w/w STIEMAZOL CREAM 1% w/w Tube of 10gm 1's 119 Ferrous salt + Folic Acid Capsule/Tablets FEFOL SPANSULE CAPSULE (150mg+0.5mg) 56's 214 Permethrin Lotion 5% Lotrix Lotion 5%w/w Bottle of 60ml 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 186 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
299	66	Cephradine Susp 125mg/5ml	GlaxoSmithKline Pakistan Limited	VELOSEF SUSP. 125MG/5ML	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (Manufacturing Site) 223 Polymyxin B (Sulphate) + Bacitracin Zinc Eye Ointment 10000IU/g + 500IU/g POLYMAX EYE	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
300	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	GlaxoSmithKline Pakistan Limited	ZYRTEC ORAL SOLUTION	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01.01.2021) It is pointed out here that clause 6 of knock down criteria stated as "samples Substandard of quoted item (Not over 5%) from (01-01-2021) if any." Our sample were declared as Misbranded which required remedial action and after rectification of labels the case has been dropped by Provincial Quality Control Board (copy of PQCB Order dated 09-02-2022 attached). Our tested sample have not been declared substandard over 5 % from 01-01-2021. Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of Short-falls 224 Polymyxin B (Sulphate) + Bacitracin Zinc Ointment 10000IU/g + 500IU/g POLYFAX SKIN Ointment (10000IU/g + 500IU/g) Tube of 20gm 1's Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01.01.2021) It is pointed out here that clause 6 of knock down criteria stated as "samples Substandard of quoted item (Not over 5%) from (01-01-2021) if any." Our samples were declared as Misbranded which required remedial action and after rectification of labels the case has been dropped by Provincial Quality Control Board (copy of PQCB Order dated 09-02-2022 attached). Our tested sample have not been declared substandard over 5 % from 01-01-2021. Our firm do not have any such information. It is requested to kindly intimate us number of such substandard batches. 243 Salbutamol (Sulfate) Solution for nebulizer 5 mg/ml VENTOLIN RESPIRATORY SOLUTION for Inhalation 5mg/ml Bottle of 20ml 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
301	68	Cetirizine Tablets 10mg	GlaxoSmithKline Pakistan Limited	ZYRTEC TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
302	76	Chlorpheniramine maleate Tablets 4 mg	GlaxoSmithKline Pakistan Limited	PIRITON TABLETS 4MG	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
303	83	Clobetasol Cream/ointment 0.05% w/w	GlaxoSmithKline Pakistan Limited	DERMOVA TE CREAM 20GM	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
304	86	Clotrimazole Skin cream 1% w/w	GlaxoSmithKline Pakistan Limited	STIEMAZOL CREAM	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
305	119	Ferrous salt + Folic Acid Capsule/Tablets	GlaxoSmithKline Pakistan Limited	FEFOL SPANSUL E CAPSULE	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
306	120	Fluconazole Capsules 150mg	GlaxoSmithKline Pakistan Limited	ZOLANIX CAPSULE 150mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no: 02: DRC of quoted product is expired.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 02: The firm provided valid DRC of quoted product, which was accepted.	
307	174	Metoclopramide (hydrochloride) Syrup 5mg/5ml	GlaxoSmithKline Pakistan Limited	MAXOLON SYRUP 5mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
308	175	Metoclopramide (hydrochloride) Tablets 10mg	GlaxoSmithKline Pakistan Limited	MAXOLON Tablets 10mg	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
309	187	Multivitamins (Tab/cap)	GlaxoSmithKline Pakistan Limited	Revitale Multi Tablets	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	
310	208	Paracetamol Syrup/Susp 160mg /5ml or less.	GlaxoSmithKline Pakistan Limited	CALPOL PAEDIATRIC SUSPENSION	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
311	209	Paracetamol Tablet 500 mg	GlaxoSmithKline Pakistan Limited	CALPOL TABLETS 500MG	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
312	214	Permethrin Lotion 5%	GlaxoSmithKline Pakistan Limited	Lotrix Lotion 5%	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	GSK Pakistan Annual Report 2021 is also attached. GlaxoSmithKline Pakistan Limited, Plot No 5, Sector 21, Korangi Industrial Area, Karachi, Pakistan	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
313	223	Polymyxin B (Sulphate) + Bacitracin Zinc Eye Ointment 10000IU/g + 500IU/g	GlaxoSmithKline Pakistan Limited	POLYFAX EYE OINTMENT	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	(Manufacturing Site) 51 Calcium Carbonate Tablets (equivalent to 400-500mg elemental calcium) CHEWCAL TABLETS (Equivalent to 400mg Elemental Calcium) 30's Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. Clause no.02: Quoted item does not comply with Advertise specification as it contains Vitamin D as additional ingredient. Punjab Procurement Rules describes prequalification of firms.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 6: The firm provided record of batches of the quoted item tested by DTLs during the stipulated period. None batch out of 57 were declared substandard rather were declared misbranded, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
314	224	Polymyxin B (Sulphate) + Bacitracin Zinc Ointment 10000IU/g + 500IU/g	GlaxoSmithKline Pakistan Limited	POLYFAX SKIN Ointment	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	At this stage, specification of items cannot be absolute. Required specifications are "Calcium Carbonate Tablets (equivalent to 400-500mg elemental calcium." Vitamin D is essential for the absorption of Calcium from the gut. Therefore, almost all the Calcium products contain Vit. D as ancillary chemical to support maximum absorption. 2. We have been offering the same formulation (and brand) in previous years against the same specification in DGHS Punjab, and our offered product (Chewcal) had been technically accepted through years being standard formulation which is internationally accepted.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted. <u>Itemwise</u> Clause no. 6: The firm provided record of batches of the quoted item tested by DTLs during the stipulated period. None batch out of 98 were declared substandard rather were declared misbranded, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
315	243	Salbutamol (Sulfate) Solution for nebulizer 5 mg/ml	GlaxoSmithKline Pakistan Limited	VENTOLIN RESPIRATORY SOLUTION	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Inq No Generic Name Quoted Brand Name, Dosage Form and Strength Pack Size Reasons of Non-qualifying Completion of Short-falls 54 Captopril Tablet 25mg CAPOTEN 25MG TABLETS 20's Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
316	245	Salbutamol Syrup	GlaxoSmithKline Pakistan Limited	VENTOLIN SYRUP	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. 58 Cefixime Suspension 100mg/5ml FIXVAL Dry Powder Susp. 100mg/5ml Bottle of 30ml 1's 59 Cefixime Suspension 200mg/5ml FIXVAL Dry Powder Susp. 200MG/5ML Bottle of 30ml 1's 60 Ceftriaxone (Sodium) Injection 1gm (I.V) TRAXON	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
317	256	Sulfamethoxazole + trimethoprim D/S Susp 400mg + 80mg/5ml	GlaxoSmithKline Pakistan Limited	SEPTRAN-DS SUSPENSION	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	INJECTION 1gm 1gm 61 Ceftriaxone (Sodium)	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
318	257	Sulfamethoxazole + Trimethoprim D/S Tablets 800mg+160mg	GlaxoSmithKline Pakistan Limited	SEPTRAN DS TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	INJECTION IV 1gm 1gm of Ceftriaxone (Sodium) Injection 250mg (I.V) TRAXON INJECTION IV 250MG 1's 62 Ceftriaxone (Sodium) Injection 500 mg (I.V) TRAXON INJECTION IV 500MG 1's 63 Cefurexime (Sodium) Injection 750mg Zinacef Injection 750mg 1's	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
319	278	Vitamin B Complex Tablets	GlaxoSmithKline Pakistan Limited	Revitale B Tablets	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Firmwise Clause no. 14: FBR Tax return of tax year 2021 not attached. Tax Return of Tax Year 2021 along with acknowledgement slip comprising 10 pages attached. GSK Pakistan Annual Report 2021 is also attached. Clause no. 02: DRAP approval of quoted pack size is not attached Pack Size (1's) &	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
320	282	Water for injection 5 ml Sterile	GlaxoSmithKline Pakistan Limited	Water for injection	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of tax year 2021 not attached.	Request to review the Technical Evaluation of Global Pharmaceutical (PVT) LTD against Inq No. 107, 268, 269 & 270 • INQ No. 107 (Domperidone 10mg Tablet) M/S Global Pharmaceutical (PVT) LTD intends to explain that Valid Data of DRAP (Approval for additional pack) of quoted pack size is being submitted with this letter. • INQ No.268 (Tramadol HCl Capsule/Tablet 50 mg) M/S Global Pharmaceutical (PVT) LTD LTD intends to explain that Tramadol HCl Capsule 50 mg is as per your specifications. Valid documents of DRAP is being submitted with this letter. • INQ No.269 (Tramadol HCl Injection 100mg/2ml) M/S Global Pharmaceutical (PVT) LTD LTD intends to explain that It was clerical mistake as our product is actually of 100mg/2ml as per your specification. Valid documents of DRAP is being submitted with this letter. • INQ No.270 (Tranexamic Acid Capsules 500mg) M/S Global Pharmaceutical (PVT) LTD intends to explain that Drug registration certificate of Tranexamic acid is attached and there renewals as per procedure duly applied . Although DRC was already furnished with parent Bid but it is again being submitted with this letter for your consideration.	<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of tax year 2021, which was accepted.
321	107	Domperidone 10mg Tablet	Global Pharmaceuticals (Pvt.) Ltd.	Pelton	Not Qualified	<u>Itemwise</u> Clause no. 02: DRAP approval of quoted pack size is not attached.		Mr. Khurram Shehzad, Business Unit Head from M/s Global Pharmaceuticals (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 02: The firm provided DRAP approval of 100's Pack, which was accepted.
322	268	Tramadol HCl Capsule/Tablet 50 mg	Global Pharmaceuticals (Pvt.) Ltd.	Rama-D	Not Qualified			Due to an inadvertent error the status of quoted item was notified "not qualified"; hence, grievance of the firm was accepted.
323	269	Tramadol HCl Injection 100mg/2ml	Global Pharmaceuticals (Pvt.) Ltd.	Rama-D	Not Qualified	<u>Itemwise</u> Clause 2 & 3: DRC of quoted item does not comply with the advertised specifications.		<u>Itemwise</u> Clause 2 & 3: The firm provided DRC of quoted item, which was accepted.
324	270	Tranexamic Acid Capsules 500mg	Global Pharmaceuticals (Pvt.) Ltd.	Transolide	Not Qualified	<u>Itemwise</u> Clause 2 & 3: The provided DRC of quoted item is expired.		<u>Itemwise</u> Clause 2 & 3: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
325	51	Calcium Carbonate Tablets (equalent to 400-500mg elemental calcium)	GSK Consumer Healthcare Pakistan Limited	Qalsium D	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of calender year 2020 is not provided. <u>Itemwise</u> Clause no. 2: Qouted specification does not comply with the advertised specifications	Kindly refer the subject report published on the website. As per report, our company has not been prequalified in subjected technical evaluation report based on certain deficiencies. The reported deficiencies and our submissions point-by-point are as under: Deficiency: FBR Tax Return For The Year 2020 Not Attached: Reply: Income tax return for the FY 2020 is attached. Deficiency: : Specification does not match (Item # 51 Calcium Carbonate 1250mg (Equivalent to 400 – 500 elemental calcium) Reply: 1. Vitamin D is essential for the absorption of Calcium from the gut. Therefore, almost all the Calcium products contain Vit. D as ancillary chemical to support maximum absorption. 2. We have been offering the same formulation (and brand) in previous years against the same specification in DGHS Punjab, and our offered product (Qalsium D) had been technically accepted through years being standard formulation which is internationally accepted. We hope all the observation / deficiencies mentioned in the prequalification evaluation report have been addressed and relevant documents have been provided to your satisfaction. You are requested to please consider the attached documents as part of our application and the status of our company may kindly be declared as "Prequalified".	Mr. Mazhar Munir, Key Account Executive from M/s GSK Consumer Healthcare Pakistan Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of calender year 2020, which was accepted. <u>Itemwise</u> Clause no. 2: The basic advertised ingredient(s) are present in the formulation of the quoted brand. As the quoted specification meets the advertised specification, the committee accepted the grievance of the firm to the extent of this parameter.
326	207	Paracetamol 80mg/0.8ml syrup/solution/drops	GSK Consumer Healthcare Pakistan Limited	Panadol Drops 30ml	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of calender year 2020 is not provided.		<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of calender year 2020, which was accepted.
327	208	Paracetamol Syrup/Susp 160mg /5ml or less.	GSK Consumer Healthcare Pakistan Limited	Panadol Liquid	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of calender year 2020 is not provided.		<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of calender year 2020, which was accepted.
328	209	Paracetamol Tablet 500 mg	GSK Consumer Healthcare Pakistan Limited	Panadol Tablet	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR Tax return of calender year 2020 is not provided.		<u>Firmwise</u> Clause no. 14: The firm provided FBR Tax return of calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
329	33	Anti-Snake venom Serum (ASV)	Hakimsons (Impex) (Private) Ltd	Snake Venom Antiserum	Not Qualified	<p><u>Itemwise</u> Clause no. 03: Quality Compliance Standards certificate of quoted product not attached.</p>	<p>Our product snake venom antiserum did not qualify in the Primary and Secondary Health, Punjab prequalification for the year 2022-23. Although we have attached all the documents, however we are attaching other documents for your kind pursuit. 01- List of countries where product exported. 02- Further to above annexure the product is deferred to the compliance of quality standard and on the grounds that it was neither WHO prequalified nor it is approved in any SRA. 03- Please check the following justification and facts about our product snake venom antiserum. 3 (i) -The snake species found in India, Pakistan, Sri Lanka, Myanmar, Afghanistan, Nepal, and Bangladesh are not found in any of the SRA countries, which is why this product is not registered in any of those countries. The product coming to the Pakistan is pertinent only to the regional species of snakes, and as such is not available in any of the SRA countries SRA countries. 3 (ii)- Central Drug Standard Control Organization: Central Drug Laboratory, Kasuli (India) which is a WHO Pre-Qualified lab gives the Lot release for every lot exported. On the basis of lot release from Kasuli, the NCL in Islamabad gives a lot release. 3 (iii)- Bharat Serum & Vaccine Limited company name is included in the List of WHO Recognized manufacturers of anti-snake venom (WHO Guidelines Management of snake bites) 3 (iv)- Attached are previous order copies of ASVS supplied by Bharat Serum & Vaccine India to the WHO 3 (v)- Bharat Serum & Vaccine is ISO (9001,14001 and 18001) Certified Company. On the basis of the above facts, we would request you to kindly pre-qualify our product for current year.</p>	<p>Mr. Muhammad Tayyab, Institutional Sales Manager from M/s Hakimsons (Impex) (Private) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 03: The firm did not provide Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO (Certificate) certificate of quoted product; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
330	7	Albendazole Tablets 200mg	Hamaz Pharmaceuticals (Pvt) Ltd.	LAREX TABLET 200MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>	<p>We are not convinced with the evaluation report as our firm has been declared "Not Qualified" by the Technical evaluation committee on following remarks; REASON OF DISQUALIFICATION (ITEM NO. 07, 19, 20, 27, 34, 35, 42, 57, 58, 59, 60, 61, 62, 67,100, 104, 118, 138, 147, 174, 175, 185, 206, 208 & 209, 28, 68, 77, 154, 167 & 199) Firm wise Clause No. 14: Incomplete FBR tax return documents are attached and turnover is less than 550 Million rupees. Item Wise Clause No. 01, The quoted product does not prequalify the criteria as prescribed in the PQ documents. Clause No. 04: Undertaking "Required storage temperature as per product's requirement is not as prescribed in PQ documents JUSTIFICATION It is intimated that to meet firm wise criteria under Clause No. 14, we had attached complete documents related to our financial soundness along with FBR tax return. But by mistake we had attached old FBR Tax Return. Now the revised Tax Return Copy has been attached. Please review our bid as our financial capacity is more than specified limit. We as per item wise criteria submitted our all technical documents so please review the documents. Undertaking to maintain required storage temperature of quoted item while transportation was attached. We are sending herewith undertaking as prescribed in PQ documents for your kind perusal and consideration. Annex 1 REASON OF DISQUALIFICATION (ITEM NO. 28) Clause No. 6: Samples substandard of quoted item (Over 5%) from 01.01. JUSTIFICATION No sample of quoted item declared substandard by DTL in specified period from 01.01.2021 REASON OF DISQUALIFICATION (ITEM NO. 68) Clause No. 2: DRC of quoted product is expired and DRAP approval of quoted pack size is not attached. JUSTIFICATION The renewal of registration</p>	<p>Mr. Amir Mehmood, Manager Account from M/s Hamaz Pharmaceuticals (Pvt) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report.</p> <p>The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
331	19	Amoxicillin (trihydrate) Capsules/tablets 250mg	Hamaz Pharmaceuticals (Pvt) Ltd.	SKYMOX CAPSULE 250MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no.01: The Quoted Product does not prequalify the criteria as prescribed in the PQ documents. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>	<p>Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no.01: Penicillin section not mentioned on GMP certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
332	20	Amoxicillin (trihydrate) Capsules/tablets 500 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	SKYMOX CAPSULE 500MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no.01: The Quoted Product does not prequalify the criteria as prescribed in the PQ documents. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>	<p>attached. JUSTIFICATION The renewal of registration certificate is attached at Page No. 472 of our Technical bid. Please review our bid and consider this point as cleared. We are sending herewith copy of registration letter, renewal and DRAP approval for quoted pack size for your kind perusal and consideration. Annex 2 REASON OF DISQUALIFICATION (ITEM NO. 77, 154, 167 & 199) Clause No. 02, DRAP approval of quoted pack size is not attached. JUSTIFICATION We are sending herewith copy of registration letter, renewal and DRAP approval for quoted pack size for your kind perusal and consideration.</p>	<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no.01: Penicillin section not mentioned on GMP certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
333	27	Amoxicillin Suspension 125mg/5ml	Hamaz Pharmaceuticals (Pvt) Ltd.	SKYMOX DRY SYRUP 125MG/5ML	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no.01: The Quoted Product does not prequalify the criteria as prescribed in the PQ documents. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>	<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no.01: Penicillin section not mentioned on GMP certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
334	28	Amoxicillin Suspension 250mg/5ml	Hamaz Pharmaceuticals (Pvt) Ltd.	SKYMOX FORTE 250MG/5ML	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no.01: The Quoted Product does not prequalify the criteria as prescribed in the PQ documents. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no.01: Penicillin section not mentioned on GMP certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>
335	34	Artemether + Lumefantrine Suspension 15 + 90 mg Susp.	Hamaz Pharmaceuticals (Pvt) Ltd.	ARTEFRO ST SUSPENSION	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
336	35	Artemether + Lumefantrine Tablets 20mg + 120mg	Hamaz Pharmaceuticals (Pvt) Ltd.	ARTEFRO ST TABLET 140MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
337	42	Azithromycin Capsules/Tab 500mg	Hamaz Pharmaceuticals (Pvt) Ltd.	HAMAZOX 500MG TABLET	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
338	57	Cefixime Capsule/Tablets 400mg	Hamaz Pharmaceuticals (Pvt) Ltd.	SUNCEF CAPSULE 400MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
339	58	Cefixime Suspension 100mg/5ml	Hamaz Pharmaceuticals (Pvt) Ltd.	SUNCEF SUSPENSION 100MG/5ML	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
340	59	Cefixime Suspension 200mg/5ml	Hamaz Pharmaceuticals (Pvt) Ltd.	SUNCEF FORTE SUSPENSION 200MG/5ML	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
341	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Hamaz Pharmaceuticals (Pvt) Ltd.	TERAXONE INJECTION 1GM	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
342	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Hamaz Pharmaceuticals (Pvt) Ltd.	TERAXONE INJECTION 250MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
343	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Hamaz Pharmaceuticals (Pvt) Ltd.	TERAXON E INJECTION 500MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
344	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	Hamaz Pharmaceuticals (Pvt) Ltd.	XERO SED SYRUP	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
345	68	Cetirizine Tablets 10mg	Hamaz Pharmaceuticals (Pvt) Ltd.	XERO SED TABLET 10MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 02: DRC of quoted product is expired and DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
346	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	NIXIN TABLET 500MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
347	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	PHONAC TABLET	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
348	104	Dimenhydrinate 50mg/ml injection	Hamaz Pharmaceuticals (Pvt) Ltd.	DRIVOL INJECTION	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
349	118	Escitalopram Tablets 10mg	Hamaz Pharmaceutical s (Pvt) Ltd.	CITALEM- 3H TABLET 10MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
350	138	Ibuprofen Susp. 100mg/5ml	Hamaz Pharmaceutical s (Pvt) Ltd.	Iburin Syrup 100mg/5ml	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
351	147	Iron iii Hydroxide Polymaltose Syrup	Hamaz Pharmaceutical s (Pvt) Ltd.	BEN-10 SYRUP	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
352	154	Levofloxacin Tablet 250mg	Hamaz Pharmaceuticals (Pvt) Ltd.	LUPIN TABLET 250MG	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
353	167	Mefenamic acid Tablet 500 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	PANAMAZ FORTE TABLET	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>
354	174	Metoclopramide (hydrochloride) Syrup 5mg/5ml	Hamaz Pharmaceuticals (Pvt) Ltd.	CLOPREL SYRUP	Not Qualified	<p>Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees.</p> <p>Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.</p>		<p><u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
355	175	Metoclopramide (hydrochloride) Tablets 10mg	Hamaz Pharmaceuticals (Pvt) Ltd.	Cloprel Tablet 10mg	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
356	185	Montelukast Tablets 10 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	MONTILAK-3H TABLET 10MG	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
357	199	Omeprazole Capsule 20mg	Hamaz Pharmaceuticals (Pvt) Ltd.	HAMAZOL CAPSULE	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 02: DRAP approval of quoted pack size is not attached. Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
358	206	Paracetamol 1 gm/100ml Infusion	Hamaz Pharmaceuticals (Pvt) Ltd.	ESTADOL IV	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
359	208	Paracetamol Syrup/Susp 160mg /5ml or less.	Hamaz Pharmaceuticals (Pvt) Ltd.	ESTADOL SYRUP	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.
360	209	Paracetamol Tablet 500 mg	Hamaz Pharmaceuticals (Pvt) Ltd.	ESTADOL TABLET	Not Qualified	Firmwise Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees. Itemwise Clause no. 04: Undertaking "Required storage temperature as per product's requirement." is not as prescribed in PQ documents.		<u>Firmwise</u> Clause no. 14: Incomplete FBR Tax return documents are attached, and turnover is less than 550 million rupees in bank statement (FY-2020-21) of the title account of the applicant firm; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 04: The firm provided undertaking "Required storage temperature as per product's requirement." as prescribed in PQ documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
361	41	Azithromycin Capsules/Tab 250mg	Herbion Pakistan (Pvt.) Ltd.	AZOVANT 250MG CAPSULE S	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.	In the Prequalification Evaluation Report for the Financial Year 2022-2023, our prequalification application is not qualified due to expired GMP Certificate. It is to inform you that we have applied for the GMP renewal on dated 12th April 2022 (Copy of the letter is attached) and since then we are continuously in coordination with DRAP for arranging the GMP Inspection of the plant. The GMP Inspection is conducted on 29th June 2022 and on 4th July 2022 and in result of inspection they issued us the GMP certificate (GMP Certificate is attached) for the period of three months.	Mr. Adnan Abdullah, Senior Strategy Manager from M/s Herbion Pakistan (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
362	42	Azithromycin Capsules/Tab 500mg	Herbion Pakistan (Pvt.) Ltd.	AZOVANT 500MG TABLET	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
363	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	Herbion Pakistan (Pvt.) Ltd.	ZANLAN ORAL SOLUTION	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
364	68	Cetirizine Tablets 10mg	Herbion Pakistan (Pvt.) Ltd.	ZANLAN TABLET	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
365	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	Herbion Pakistan (Pvt.) Ltd.	LACNOVE X SYRUP	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
366	154	Levofloxacin Tablet 250mg	Herbion Pakistan (Pvt.) Ltd.	EFLOXIN 250MG TABLET	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
367	185	Montelukast Tablets 10 mg	Herbion Pakistan (Pvt.) Ltd.	MONTELO 10MG TABLET	Not Qualified	<u>Firmwise</u> Clause no. 03: GMP certificate Expired <u>Itemwise</u> Clause no.01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
368	2	Acetylsalicylic acid 75mg enteric coated tab.	Highnoon Laboratories Lth	LOPRIN	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.	With reference of technical evaluation report as per Clause no. 03: Complete Quality Management System documents are not provided. At the time of online submission some pages were not scan properly. Now we are enclosing herewith complete QMS data. As per above said facts kindly accept our grievance and oblige.	Mr. Amjad Iqbal, Distributor from M/s Highnoon Laboratories Lth attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
369	37	Atenolol Tablet 50mg	Highnoon Laboratories Lth	BLOKIUM	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
370	38	Atorvastatin Tablets 20mg	Highnoon Laboratories Lth	LIPIREX	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
371	85	Clopidogrel Tablets 75 mg	Highnoon Laboratories Lth	PIDOGREL	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
372	90	Daclatasvir 60mg Tablet	Highnoon Laboratories Lth	DACLATA	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
373	249	Sitagliptin 50mg Tablet	Highnoon Laboratories Lth	TAGIP	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
374	252	Sofosbuvir 400mg Capsule/Tablet	Highnoon Laboratories Lth	FOSBU	Not Qualified	<u>Firmwise</u> Clause no. 03: Complete Quality Management System documents are not provided.		<u>Firmwise</u> Clause no. 03: The firm provided Complete Quality Management System document, which was accepted.
375	270	Tranexamic Acid Capsules 500mg	Hilton Pharma (Pvt.) Limited	TRANSAMIN	Not Qualified	<u>Itemwise</u> Clause no. 2 & 3: DRAP approval of quoted pack not attached.	With reference to your Technical evaluation report, Our item sr. no. 723 / Inq no. 270 Tranexamic Acid Capsule 500mg (cap Transamin 500mg) as online portal. Due to item wise clause no. 2 and 3 DRAP approval of quoted pack not attached. We are submitting the DRAP registration with complete trail. As per above said facts kindly prequalify our product and oblige.	Mr. Amjad Iqbal, Distributor from M/s Hilton Pharma (Pvt.) Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 2 & 3: The firm provided DRAP approval of 20's Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
376	16	Amlodipine Tablets 5 mg	Himont Pharmaceutical Private Limited	Cardiosil	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.	We Himont Pharmaceutical Pvt Ltd Pakistan are renowned pharmaceutical manufacturing company having good alliance with Govt. and semi-Government institute for the supply of our quality products at economical rates. We Himont Pharmaceutical Private Limited participated in DGHS Prequalification of drugs and medicine for FY 2022-23 and declared Non-responsive against all quoted items due to Non-Provision Valid CGMP. We are submitting the valid CGMP as per your requirements and request you to declare us Pre-qualified bidder to ensure healthy competition between bidders in procurement of medicine.	Mr. Yasir Ali, Distributor of M/s Himont Pharmaceutical Private Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
377	38	Atorvastatin Tablets 20mg	Himont Pharmaceutical Private Limited	Atrocard	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
378	41	Azithromycin Capsules/Tab 250mg	Himont Pharmaceutical Private Limited	Azomont	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
379	42	Azithromycin Capsules/Tab 500mg	Himont Pharmaceutical Private Limited	Azomont	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
380	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Himont Pharmaceutical Private Limited	Orcid	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
381	126	Glimepiride Tablets 2mg	Himont Pharmaceutical Private Limited	Pamaryl	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
382	148	Iron Sucrose Injection 100mg/5ml	Himont Pharmaceutical Private Limited	Heamocare SS	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
383	187	Multivitamins (Tab/cap)	Himont Pharmaceutical Private Limited	VC-CAL plus	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
384	199	Omeprazole Capsule 20mg	Himont Pharmaceutical Private Limited	Klofix	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
385	219	Phloroglucinol Hydrate 40mg + Trimethyl Phloroglucinol 0.04mg Injection	Himont Pharmaceutical Private Limited	Spasfon	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
386	220	Phloroglucinol Hydrate 80mg + Trimethyl Phloroglucinol 80mg tablets	Himont Pharmaceutical Private Limited	Spasfon	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
387	249	Sitagliptin 50mg Tablet	Himont Pharmaceutical Private Limited	Gliptin	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.
388	270	Tranexamic Acid Capsules 500mg	Himont Pharmaceutical Private Limited	Hixamic	Not Qualified	<u>Firmwise</u> Clause No. 03: GMP Certificate Expired. <u>Itemwise</u> Clause No. 01: Quoted item section on GMP not prequalified due to expired certificate.		<u>Firmwise</u> Clause No.03: The firm provided valid GMP certificate, which was accepted. <u>Itemwise</u> Clause No.01: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
389	214	Permethrin Lotion 5%	Hiranis Pharmaceuticals (Pvt.) Ltd	PLAVEO	Not Qualified	<u>Itemwise</u> Clause No.01: Quoted item section not enlisted on GMP certificate.	After Technical Evaluation our 13 products recommended for prequalification whereas three products were not prequalified due to some specific reasons. We have reviewed the remarks of Technical Evaluation Committee mentioned clause wise in Prequalification Evaluation report and would like to present our grievance in this regard. Please note our reply in favor of our grievance product wise. Inquiry No. 214:Permethrin lotion 5%: Clause No. 1: Quoted Item section not listed in GMP Certificate. Reply: The Schedule B-1 of Drugs (L.R & Advertising) Rules, 1976 has outlined about "Requirements of Plant and Equipments" for manufacturing of drugs by way of formulation. In this requirement mentioned in (A) directing about section and equipments required for manufacturing of drugs fall in category of External appliances and suspense. The semisolids dosage forms (Cream/Ointment/Gel/Paste) and Lotions falls in category of external appliances and suspense and can be manufactured in same section. The DRAP has approved our manufacturing sections and said dosage form (Lotion) for manufacturing accordingly. (Copy of Schedule B-1 of Drugs (L.R & Advertising) Rules, 1976 attached for reference). Annexure A Inquiry No. 229: Prednisolone tablet 5mg: Clause No. 2: DRC not attached. Reply: It is respectfully submitted that we have already attached the DRC in pre-qualification documents as well uploaded in PQD portal. However we once again providing the DRC of Inflagic Tablet 5mg (Prednisolone) for reference (copy attached). Annexure B. Clause No. 3: Experience of quoted item of manufacturer from date of registration is less than one year. Reply: It is respectfully submitted that the	Mr. Rashid Butt, Business Manager from M/s Hiranis Pharmaceuticals (Pvt.) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause No.01: Relevant section was mentioned in the valid GMP certificate, which was accepted.
390	229	Prednisolone Tablets 5mg	Hiranis Pharmaceuticals (Pvt.) Ltd	INFLAGIC	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached. Clause No.03: Experience of quoted item of manufacturer from date of registration is less than one year. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	directing about section and equipments required for manufacturing of drugs fall in category of External appliances and suspense. The semisolids dosage forms (Cream/Ointment/Gel/Paste) and Lotions falls in category of external appliances and suspense and can be manufactured in same section. The DRAP has approved our manufacturing sections and said dosage form (Lotion) for manufacturing accordingly. (Copy of Schedule B-1 of Drugs (L.R & Advertising) Rules, 1976 attached for reference). Annexure A Inquiry No. 229: Prednisolone tablet 5mg: Clause No. 2: DRC not attached. Reply: It is respectfully submitted that we have already attached the DRC in pre-qualification documents as well uploaded in PQD portal. However we once again providing the DRC of Inflagic Tablet 5mg (Prednisolone) for reference (copy attached). Annexure B. Clause No. 3: Experience of quoted item of manufacturer from date of registration is less than one year. Reply: It is respectfully submitted that the	<u>Itemwise</u> Clause No.02: The firm provided DRC of quoted item, which was accepted. Clause No.03: The experience of quoted item of manufacturer from date of registration is more than one year; hence, grievance of the firm was accepted to the extent of this parameter. Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 34 batches were manufactured out of which 2 were declared substandard, therefore, percentage of batches declared substandard was above 5%. ; hence, grievance of the firm was not accepted to the extent of this parameter.
391	249	Sitagliptin 50mg Tablet	Hiranis Pharmaceuticals (Pvt.) Ltd	VIASIT	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached. Clause No.03: Experience of quoted item of manufacturer from date of registration is less than one year.	directing about section and equipments required for manufacturing of drugs fall in category of External appliances and suspense. The semisolids dosage forms (Cream/Ointment/Gel/Paste) and Lotions falls in category of external appliances and suspense and can be manufactured in same section. The DRAP has approved our manufacturing sections and said dosage form (Lotion) for manufacturing accordingly. (Copy of Schedule B-1 of Drugs (L.R & Advertising) Rules, 1976 attached for reference). Annexure A Inquiry No. 229: Prednisolone tablet 5mg: Clause No. 2: DRC not attached. Reply: It is respectfully submitted that we have already attached the DRC in pre-qualification documents as well uploaded in PQD portal. However we once again providing the DRC of Inflagic Tablet 5mg (Prednisolone) for reference (copy attached). Annexure B. Clause No. 3: Experience of quoted item of manufacturer from date of registration is less than one year. Reply: It is respectfully submitted that the	<u>Itemwise</u> Clause No.02: The firm provided DRC of quoted item, which was accepted. Clause No.03: The Experience of quoted item of manufacturer from date of registration is more than one year; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
392	57	Cefixime Capsule/Tablets 400mg	ICI Pakistan Limited	Corinef Capsule 400 mg	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	As per the technical evaluation report, all our quoted products are prequalified except Corinef Capsule 400 mg (cefixime) due to the substandard samples as per clause 6 of the prequalification documents. Sir, none of our quoted products declared substandard and all the required undertakings were part of the submitted bid, copy attached. However, the product found misbranded and later on the case was discussed/resolved by the PQCB. Therefore, we request you to please re-evaluate the matter and consider our product as responsive/qualified. Besides, our team is also available to address and explain all the concerns you have.	Mr. Munim Khan, Distributor of M/s ICI Pakistan Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. Among the batches manufactured none declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
393	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Indus Pharma Pvt Ltd	Dyclo 75mg Inj	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	Reference to your PQ Technical Evaluation report dated: 01/07/2022, your evaluation committee declare our quoted item No. 101 Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule (Dyclo 75mg Inj.) not Qualified due to Samples Substandard of quoted item (over 5%) from 01-01-2021. Sir, We M/S Indus Pharma Pvt Ltd. would like to bring your kind attention that we did not supply our quoted item Dyclo 75mg Inj. in Govt. Institution of Punjab from 01-01-2021 till today, so how it is possible that our quoted product samples declared substandard by Punjab DTL, there must be some misunderstanding/confusion by your evaluation committee.	Mr. Munim Khan, Distributor of M/s Indus Pharma Pvt Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 688 batches were manufactured out of which 1 declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
394	57	Cefixime Capsule/Tablets 400mg	Linz Pharmaceuticals (Pvt) Ltd	Linzim	Not Qualified	<u>Itemwise</u> Clause No.02: DRC/Renewal Application without fee challan copy	As per your findings the following items are not qualified, because of missing DRC / Renewal application without fee challan copy of quoted items; Item # 57 Cefixime Capsule 400mg (Linzim). Item # 59 Cefixime Suspension 200mg/5ml (Linzim). We are again submitted valid DRC / renewal application with fee challan copies of above mentioned items for your kind consideration and record.	Mr. Shahid Iqbal, Sales Manager from M/s Linz Pharmaceuticals (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause No.02: The firm provided valid DRC of quoted item, which was accepted
395	59	Cefixime Suspension 200mg/5ml	Linz Pharmaceuticals (Pvt) Ltd	Linzim	Not Qualified	<u>Itemwise</u> Clause No.02: DRC/Renewal Application without fee challan copy		<u>Itemwise</u> Clause No.02: The firm provided valid DRC of quoted item, which was accepted
396	7	Albendazole Tablets 200mg	Lisko Pakistan (Pvt) Ltd	ALBENDAZOLE TABLET 200MG	Not Qualified	<u>Itemwise</u> Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.	Grievance no# 1: Inq no# 23 "Amoxicillin + Clavulanic Acid Suspension 125 mg + 31.25 mg / 5 ml" Objections / remarks in prequalification evaluation report: DRC/Renewal not attached. Grievance & clarification along with supportive documents: We are again submitting DRC / Renewal for your kind consideration. Kindly prequalify our quoted product. Grievance no# 2: Inq no# 160 "Losartan Potassium Tablet 50mg (30's)" Objections / remarks in prequalification evaluation report: DRAP approval of quoted pack not attached Grievance & clarification along with supportive documents: We are again submitting pack approval of 30's by DRAP for your kind consideration. Kindly prequalify our quoted pack size of quoted product. Grievance no# 3: Inq no# 7 "Albendazole tablet 200mg" Objections / remarks in prequalification evaluation report: Experience of quoted item of manufacturer from date of registration is less than one year Grievance & clarification along with supportive documents: We request you to kindly re-check experience of quoted item from the date of registration for quoted products "Albendazole tab 200mg" against Inq no# 7 and "Sitagliptin 50mg tab" against inq no#249 as both products have experience of 1 year since date of registration. Kindly prequalify our quoted products. Grievance no# 4: Inq no# 249 "Sitagliptin 50mg Tablet" Objections / remarks in prequalification evaluation report: Experience of quoted item of manufacturer from date of registration	Dr. Sarfaraz, Business Manager from M/s Lisko Pakistan (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
397	7	Albendazole Tablets 200mg	Lisko Pakistan (Pvt) Ltd	ALBENDAZOLE TABLET 200MG	Not Qualified	<u>Itemwise</u> Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.		<u>Itemwise</u> Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
398	23	Amoxicillin + Clavulanic Acid Suspension 125 mg + 31.25 mg / 5 ml	Lisko Pakistan (Pvt) Ltd	AUGMICLAVE SYP. 156.25MG	Not Qualified	<u>Itemwise</u> Clause No.02: DRC/Renewal not attached.	<u>Itemwise</u> Clause No.02: The firm provided valid DRC of quoted item, which was accepted.	
399	23	Amoxicillin + Clavulanic Acid Suspension 125 mg + 31.25 mg / 5 ml	Lisko Pakistan (Pvt) Ltd	AUGMICLAVE SYP. 156.25MG	Not Qualified	<u>Itemwise</u> Clause No.02: DRC/Renewal not attached.	<u>Itemwise</u> Clause No.02: The firm provided valid DRC of quoted item, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
400	109	Doxycycline (hyclate) Capsules 100mg	Lisko Pakistan (Pvt) Ltd	LIBRACIN CAPS 100mg	Not Qualified	Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	is less than one year Grievance & clarification along with supportive documents: We request you to kindly re-check experience of quoted item from the date of registration for quoted products "Albendazole tab 200mg" against Inq no# 7 and "Sitagliptin 50mg tab" against inq no#249 as both products have experience of 1 year since date of registration. Kindly prequalify our quoted products. Grievance no# 5: Inq no# 284 "ZINKROL 20mg/5ml SYRUP" Objections / remarks in prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	The firm did not contest for the quoted item.
401	160	Losartan Potassium Tablet 50mg	Lisko Pakistan (Pvt) Ltd	LOZARTA TABLET 50MG	Not Qualified	Itemwise Clause No.02: DRAP approval of quoted pack not attached	against inq no#249 as both products have experience of 1 year since date of registration. Kindly prequalify our quoted products. Grievance no# 5: Inq no# 284 "ZINKROL 20mg/5ml SYRUP" Objections / remarks in prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause No.02: The firm provided DRAP approval of 30's Pack, which was accepted.
402	249	Sitagliptin 50mg Tablet	Lisko Pakistan (Pvt) Ltd	SITAGLIPT IN TAB 50mg	Not Qualified	Itemwise Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
403	249	Sitagliptin 50mg Tablet	Lisko Pakistan (Pvt) Ltd	SITAGLIPT IN TAB 50mg	Not Qualified	Itemwise Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
404	249	Sitagliptin 50mg Tablet	Lisko Pakistan (Pvt) Ltd	SITAGLIPT IN TAB 50mg	Not Qualified	Itemwise Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
405	249	Sitagliptin 50mg Tablet	Lisko Pakistan (Pvt) Ltd	SITAGLIPT IN TAB 50mg	Not Qualified	Itemwise Clause No.03: experience of quoted item of manufacturer from date of registration is less than one year.	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
406	284	Zinc Sulphate Syrup 20mg/5ml.	Lisko Pakistan (Pvt) Ltd	Zinc Sulphate Syrup 20mg/5ml	Not Qualified	Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 107 batches were manufactured out of which 5 were declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
407	284	Zinc Sulphate Syrup 20mg/5ml.	Lisko Pakistan (Pvt) Ltd	Zinc Sulphate Syrup 20mg/5ml	Not Qualified	Itemwise Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	prequalification evaluation report: Samples Substandard of quoted item (over 5%) from (01-01-2021). Grievance & clarification along with supportive documents: We would like to bring in your kind knowledge that we have 2 different registration of "Zinc sulphate 20mg/5ml" registered by DRAP, Islamabad with different packaging, different formulation, different finished specs and different testing method (Both registration letters attached). Product with registration no# 092905 having USP specs applied for prequalification 2022-23 while product with registration no# 086949 having IP specs has been applied for de-registration in drap. We are submitting detailed evidences that product with Reg no# 086949 (IP Specs)" declared sub-standard by DTLs of Punjab. Our Product with USP specs having DRC no# 092905 has never been declared sub-standard by any DTL of Pakistan since date of registration (undertaking on stamp paper attached). % of sub-standard declared samples against total manufactured batches Since Jan 2021 of our quoted product "Zinkrol Syrup 20mg/5ml USP specs (Reg no# 092905) is 0%. So, we request you to kindly prequalify our quoted product as per standard criteria. We request you to kindly prequalify all above mentioned quoted items and quoted pack sizes as we are submitting all supportive documents against your objection raised in pre-qualification evaluation report.	Itemwise Clause no. 6: The representative of the firm claimed that none of the sample of 60ml pack size was declared substandard by DTL, and the same was checkrd and found correct by the committee; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
408	285	Zinc Sulphate Tablets 20 mg	Lisko Pakistan (Pvt) Ltd	ZINKROL tablet	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached		The firm did not contest for the quoted item.
409	285	Zinc Sulphate Tablets 20 mg	Lisko Pakistan (Pvt) Ltd	ZINKROL tablet	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached		The firm did not contest for the quoted item.
410	285	Zinc Sulphate Tablets 20 mg	Lisko Pakistan (Pvt) Ltd	ZINKROL tablet	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached		The firm did not contest for the quoted item.
411	285	Zinc Sulphate Tablets 20 mg	Lisko Pakistan (Pvt) Ltd	ZINKROL tablet	Not Qualified	<u>Itemwise</u> Clause No.02: DRC not attached		The firm did not contest for the quoted item.
412	272	Typhoid Conjugate Vaccine WHO Pre-qualified	M & M Pharma.	Typhibev	Not Qualified	<u>Itemwise</u> Clause No.03: Experience of quoted item of manufacturer from date of registration is less than one year		Mr. Raheel Munawar, Director Marketing from M/s M & M Pharma. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause No.03: The experience of quoted item of manufacturer from date of registration is less than one year; hence, grievance of the firm was not accepted to the extent of this parameter.
413	38	Atorvastatin Tablets 20mg	Macter International Limited	Tavist 20mg Tablet	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.	We have submitted the (On-Line & Hard Copy) undertaking along with valid calibration certificates of 7 Stability Chambers of F-216 plant in our Pre-Qualification Application and again attached with this letter for your kind consideration. You are requested to kindly pre-qualify our F-216 plant and its offered products for healthy competition.	Mr. Syed Mumtaz Haider Zaidi, General Manager from M/s Macter International Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
414	57	Cefixime Capsule/Tablets 400mg	Macter International Limited	Maxima Caps 400mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
415	58	Cefixime Suspension 100mg/5ml	Macter International Limited	Maxima Dry Susp 100mg/5ml	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
416	59	Cefixime Suspension 200mg/5ml	Macter International Limited	Maxima DS Dry Susp 200mg/5ml	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
417	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Macter International Limited	Titan Inj 1g (IV)	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
418	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Macter International Limited	Titan Inj 250mg (IV)	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
419	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Macter International Limited	Titan Inj 500mg (IV)	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
420	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Macter International Limited	Ciproquine Tabs 500mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
421	80	Ciprofloxacin Injection 200mg / 100ml	Macter International Limited	Ciproquine Inf 200mg/100 ml	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
422	81	Clarithromycin Suspension 125mg/5ml	Macter International Limited	Ultima Dry Susp 125mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		The firm did not contest for the quoted item.
423	82	Clarithromycin Tablets 500mg	Macter International Limited	Ultima Tabs 500mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
424	85	Clopidogrel Tablets 75 mg	Macter International Limited	Locril Tabs 75mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
425	90	Daclatasvir 60mg Tablet	Macter International Limited	Maclinza Tabs 60mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
426	114	Enticavir 0.5mg tab	Macter International Limited	Ecavir Tabs 0.5mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
427	117	Erythropoietin 4000-5000 I.U Injection Vial/Pre-filled syringe	Macter International Limited	Epocan Inj 4000 IU	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
428	126	Glimepiride Tablets 2mg	Macter International Limited	Glio Tabs 2mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
429	185	Montelukast Tablets 10 mg	Macter International Limited	MNTK Tab 10mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
430	188	Nalbuphine Hcl Injection 10mg/ml	Macter International Limited	BUPHAIN INJ 10MG (BLISTER)	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
431	199	Omeprazole Capsule 20mg	Macter International Limited	Sante Caps 20mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
432	241	Salbutamol (Sulfate) 100 micrograms and beclomethasone 50mcg inhaler	Macter International Limited	Salnon Inh	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
433	242	Salbutamol (Sulfate) Inhaler 100 micrograms	Macter International Limited	Inspiro Inh 100mcg - HFA	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
434	263	Tenofovir (disoproxil fumarate) 300 mg	Macter International Limited	Vireof Tab 300mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
435	268	Tramadol HCl Capsule/Tablet 50 mg	Macter International Limited	Ramol Caps 50mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
436	269	Tramadol HCl Injection 100mg/2ml	Macter International Limited	Ramol Inj 100mg/2ml	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
437	279	Vitamin D3 Injection 5mg	Macter International Limited	DX3 Inj. 5mg	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
438	281	Water for injection 10 ml Sterile	Macter International Limited	Water for injection 10 ml Sterile	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached. <u>Itemwise</u> Clause no.2:Application for renewal of Drug registration certificate not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted. <u>Itemwise</u> Clause no.2: The provided application for renewal of Drug registration certificate, which was accepted.
439	282	Water for injection 5 ml Sterile	Macter International Limited	Water for injection 05 ml Sterile	Not Qualified	<u>Firmwise</u> clause no 12: calibration/validation record of stability chambers at manufacturing site F-216 not attached.		<u>Firmwise</u> clause no 12: The firm provided calibration certificates of stability chambers at manufacturing site F-216, which were accepted.
440	16	Amlodipine Tablets 5 mg	Martin Dow Marker Ltd	LODOPIN	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached.	We have come to know through Prequalification Evaluation Report uploaded on the website of Punjab Secondary Healthcare Department, Lahore that we have been given some fewer documents/and due to Typo error we declared as "dis-Qualified"	Mr. Muhammad Farrukh Javed, Institutional Regional Manager from M/s Martin Dow Marker Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> clause no 12: The firm provided calbration certificatess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
441	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	Martin Dow Marker Ltd	COSOME-E	Not Qualified	Firm wise: Clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
442	41	Azithromycin Capsules/Tab 250mg	Martin Dow Marker Ltd	ARZOMIC	Not Qualified	Firm wise: Clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
443	42	Azithromycin Capsules/Tab 500mg	Martin Dow Marker Ltd	ARZOMIC	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
444	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Martin Dow Marker Ltd	MERCIP	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
445	82	Clarithromycin Tablets 500mg	Martin Dow Marker Ltd	KLARIBAC T	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
446	109	Doxycycline (hyclate) Capsules 100mg	Martin Dow Marker Ltd	SUPRAMY CIN-100	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached. Item wise: clause no 2:The drug registration certificate provided for the item doxycycline HCL instead of docycline hyclate Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> clause no 12: The firm provided calbration certificatess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted. <u>Itemwise</u> clause no 2: The firm provided DRC of the quoted item, which was accepted. Clause no. 6: The firm provided record of batches of the quoted item tested by DTLs during the stipulated period. None batch out of 35 were declared substandard rather were declared misbranded, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
447	118	Escitalopram Tablets 10mg	Martin Dow Marker Ltd	PEXNEW	Not Qualified	Firm wise: clause no 12:Calbration /validation record of stabaility chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
448	119	Ferrous salt + Folic Acid Capsule/Tablets	Martin Dow Marker Ltd	SANGOBIO N	Not Qualified	Firm wise: Manufacturing site mentioned on renewal application for registration is Martin Dow Marker Karachi with approved GMP section for soft gelatin capsule.However,the firm quoted Marker dow marker Ltd Quetta as manufacturing site. Clause no 14: FBR return for calender year 2020 not attached. Item wise: Cause no 2:The quoted item Sangobion contains ingredients in addition to item advertised Ferrous sulphate+ Folic acid. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no 14: The firm provided FBR return for calender year 2020, which was accepted. <u>Itemwise</u> Clause no 2: The basic advertised ingredient(s) are present in the formulation of the quoted brand. As the quoted specification meets the advertised specification, the committee accepted the grievance of the firm to the extent of this parameter. The firm provided approved GMP section for soft gelatin capsule, which was accepted. Clause no. 6: The firm provided record of batches of the quoted item tested by DTLs during the stipulated period. None batch out of 46 were declared substandard rather were declared misbranded, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
449	126	Glimepiride Tablets 2mg	Martin Dow Marker Ltd	GLIOPTIM	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
450	154	Levofloxacin Tablet 250mg	Martin Dow Marker Ltd	LEVOMER C	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
451	171	Metformin (hydrochloride) Tablets 500mg	Martin Dow Marker Ltd	GLUCOPH AGE	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.
452	185	Montelukast Tablets 10 mg	Martin Dow Marker Ltd	WHIZIX	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached. Item wise: clause no.2:The Drug registration certificate not provided for quoted pack size 20s.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted. <u>Itemwise</u> clause no.2: The firm provided DRAP approval of 14's Pack, which was accepted.
453	187	Multivitamins (Tab/cap)	Martin Dow Marker Ltd	MULTIBIO NTA	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached Clause no 14: FBR return for calender year 2020 not attached.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatsess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
454	279	Vitamin D3 Injection 5mg	Martin Dow Marker Ltd	ADVIT-D	Not Qualified	Firm wise: clause no12:Calbration /validation record of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta not attached. Clause no 14: FBR return for calender year 2020 not attached. Item wise: Clause no 2: The quoted item ADVIT Injection with strength 3mg did not comply with advertised spcification.		<u>Firmwise</u> clause no 12: The firm provided calbration certificatess of stability chamber of manufacturing site Martin Dow Marker Ltd Quetta, which were accepted. Clause no 14: The firm provided FBR return for calender year 2020, which was accepted. <u>Itemwise</u> Clause no 2: The quoted item ADVIT Injection with strength 3mg did not comply with advertised spcification; hence, grievance of the firm was not accepted to the extent of this parameter.
455	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Martindow Limited	Linesta Tablets	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.	We have participated for Pre-Qualification of manufactured products along with Imported items (as Sole agent) with proper adequate of performance to fulfill the documentary requirements as per evaluation criteria, whereas we have been rejected to provide the updated cGMP certificate. Clause 03: GMP certificate For which we are submitting the following documents for your review & further acceptance our grievance, <input type="checkbox"/> Request for issuance of cGMP (Received by DRAP authorities on dated: 07-06-2022) <input type="checkbox"/> Fee Challan of Rs. 50,000/- in request for renewal of cGMP. (Submitted in Bank on dated: 03-06-2022) <input type="checkbox"/> Routine GMP inspection by FID-II DRAP, Karachi, by Mr. Abdul Rusool Sheikh (on dated: 20-10-2021) <input type="checkbox"/> Panel Inspection (Grant of Renewal of Drug Manufacturing License) on dated: 08-07-2021 (submitted in account for issuance of cGMP) <input type="checkbox"/> Updated Drug Manufacturing License. (Based on above report) in which authorities has clearly mentioned about compliance of our CGMP in support of issuance of certificate. (Date of issuance of DML: 14-09-2021) <input type="checkbox"/> Panel inspection (cGMP Audit Proforma / GMP compliance inspection) on dated: 07-05-2019 CGMP Certificate (Date of issuance: 11-06-2020) Valid for 02 Year from the date of issuance. Based on the above provided data by authorities, it has been well concluded that, overall cGMP compliance towards maintenance & working of equipment's, production procedures, QC facilities. M/S. Martin Dow Limited is operating at good level of compliance with cGMP guidelines as per Drug Act	Mr. Zaheer Abbas, Sales Manager from M/s Martindow Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.
456	99	Diazepam Injection 10mg	Martindow Limited	Valium Ampoules	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.	Panel Inspection (Grant of Renewal of Drug Manufacturing License) on dated: 08-07-2021 (submitted in account for issuance of cGMP) <input type="checkbox"/> Updated Drug Manufacturing License. (Based on above report) in which authorities has clearly mentioned about compliance of our CGMP in support of issuance of certificate. (Date of issuance of DML: 14-09-2021) <input type="checkbox"/> Panel inspection (cGMP Audit Proforma / GMP compliance inspection) on dated: 07-05-2019 CGMP Certificate (Date of issuance: 11-06-2020) Valid for 02 Year from the date of issuance. Based on the above provided data by authorities, it has been well concluded that, overall cGMP compliance towards maintenance & working of equipment's, production procedures, QC facilities. M/S. Martin Dow Limited is operating at good level of compliance with cGMP guidelines as per Drug Act	<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.
457	118	Escitalopram Tablets 10mg	Martindow Limited	Safepram Tablets	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.	Panel Inspection (Grant of Renewal of Drug Manufacturing License) on dated: 08-07-2021 (submitted in account for issuance of cGMP) <input type="checkbox"/> Updated Drug Manufacturing License. (Based on above report) in which authorities has clearly mentioned about compliance of our CGMP in support of issuance of certificate. (Date of issuance of DML: 14-09-2021) <input type="checkbox"/> Panel inspection (cGMP Audit Proforma / GMP compliance inspection) on dated: 07-05-2019 CGMP Certificate (Date of issuance: 11-06-2020) Valid for 02 Year from the date of issuance. Based on the above provided data by authorities, it has been well concluded that, overall cGMP compliance towards maintenance & working of equipment's, production procedures, QC facilities. M/S. Martin Dow Limited is operating at good level of compliance with cGMP guidelines as per Drug Act	<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
458	125	Glibenclamide Tablets 5mg	Martindow Limited	Euglucon Tablets	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.	compliance with cGMP guidelines as per Drug Act, 1976/DRAP Act 2012, and rules frame there under. As the request has been accepted & proceeded in favor of M/S. Martin Dow Limited, based on current panel inspection by DRAP Team & we assure to your good self to submit our cGMP Certificate ASAP we receive from DRAP Authorities. Clause 14: FBR returns for calendar year 2018 & 2020 attached As per requirement in attachment section of Firm Document, we have submitted Tax Return FY 2018-2019 along with Bank statement, now as per your requirement we are submitting the return for 03 Years. (2018-2019-2020) for your review as well. We are Looking forward to competent authorities to accept our provided documents & approved our product as Pre-Qualified in DGHS Punjab Pre-Qualification FY 2022-2023.	<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.
459	154	Levofloxacin Tablet 250mg	Martindow Limited	Fuvelox Tablets	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.		<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.
460	181	Midazolam Injection 1mg/ml	Martindow Limited	Dormicum Ampoules	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.		<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.
461	190	Naproxen Sodium Tablet 550 mg (equivalent to 500mg Naproxen)	Martindow Limited	Synflex Tablets	Not Qualified	Firmwise: Clause No.03: GMP certificate expired. Clause No.14:FBR returns for calender year 2018&2020 not attached.		<u>Firmwise</u> Clause No.03: The firm provided GMP Inspection Report issued by DRAP; hence, grievance of the firm was accepted to the extent of this parameter. Clause No.14: The firm provided FBR returns for calender year 2018 & 2020, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
462	3	Acyclovir Injection 250 mg	MTI Medical Pvt Ltd	Arpes 250mg Lyophilized Injection	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.	MTI Medical (Pvt.) Ltd has been declared non-responsive due to the following reasons: Firm Wise: • Clause No 17: Undertaking Submitted Not In Accordance With Advertised Criteria. • Clause No 22: Notarized Undertaking Not Attached. Item Wise: • Clause No 5: Undertaking Not In Accordance With Advertised Criteria. We want to put our stance against these decisions as under: Firm Wise: • Clause No 17: We had submitted Undertaking that none of our batch has been declared spurious/adulterated , we are again attaching this undertaking which fulfills the advertised criteria of PQOD. • Clause No 22: We had submitted that we accept all the terms and conditions of Prequalification Documents on notarized stamp paper, we are again submitting this undertaking on notarized stamp paper. Item Wise: • Clause No 5: We had submitted the undertaking for clause 4 to 11 on notarized stamp paper, we are again submitting this undertaking according to advertised criteria of PQOD.	Mr. Khurram Shahzad, Business Unit Head from M/s MTI Medical Pvt Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
463	4	Acyclovir Injection 500 mg	MTI Medical Pvt Ltd	ARPES 500 MG LYOPHILIZED INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.	For product Sr. # 1076 Inq # 106 Dobutamine , our product has been declared non responsive due to Clause No 2: The quoted item Dobutamine 200mg/50 ml did not comply with advertised specification , we want to put our stance as follow: • We, MTI Medical (Pvt.) Ltd., are manufacturers of Pharmaceutical products. Our product Tobuject Injection 250mg (Dobutamine) is registered by Drug Regulatory Authority of Pakistan with registration number 094025 (Drug Registration Certificate attached) as per the USP Specifications mentioned below: Each 20ml vial contains Dobutamine (as HCl) 250mg (USP Specifications) • Our product follows the USP Specifications and is according to the international FDA Standards and guidelines. We are attaching a complete detail of the international FDA Approved products of Dobutamine having same specifications	<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
464	10	Amikacin (Sulphate) Injection 100mg	MTI Medical Pvt Ltd	Mikaton 100 mg Injection	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22:Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
465	41	Azithromycin Capsules/Tab 250mg	MTI Medical Pvt Ltd	ZECMO CAPSULE S 250 MG	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.	products of Dobutamine having same specifications as our product Tobject Injection 250mg for your reference. We are also attaching USP Product monograph for Dobutamine injection. • Moreover, we were prequalified in PQOD 2021-2022 with the same specifications and are serving different DHA's of Punjab with our product.(Reference Attached) For Product Sr #1077 Inq # 108 Dopamine, our product has been declared non responsive due to Drug Registration Certificate for quoted pack size 1's not attached. We had attached DRC of Dopamine for Pack size of 1's, and are again attaching it for your record. Hence our product with pack size of 1's also fulfills the advertised criteria of PQOD prequalification. For Product Sr # 1091 Inq # 170 Meropenem 1 G, Product Sr # 1097 Inq # 260 Tazopride Sterile Powder 2.25 Gm, Product Sr # 1098 Inq # 261 Tazopride Sterile Powder 4.5 Gm our product has been declared not qualified due to Clause no 7,8,9,10,11,12,16,17, Undertaking of contract manufacturing not provided. Clause no 12: Calibration/Validation record of stability chambers of contract manufacturer not attached. Clause no 15: Building Fitness certificate/layout plan of contract manufacturer not attached. We are again attaching all the above undertakings and documents which will fulfill all the criteria of PQOD prequalification	<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
466	42	Azithromycin Capsules/Tab 500mg	MTI Medical Pvt Ltd	ZECMO 500 MG TABLET	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
467	43	Azithromycin Susp 200mg/5ml	MTI Medical Pvt Ltd	ZECMO ORAL SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
468	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	MTI Medical Pvt Ltd	CYTOZON 1 GM INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
469	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	MTI Medical Pvt Ltd	CYTOZON 250 MG INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
470	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	MTI Medical Pvt Ltd	CYTOZON 500 MG INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
471	63	Cefurexime (Sodium) Injection 750mg	MTI Medical Pvt Ltd	ROKKY 750 MG INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
472	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	MTI Medical Pvt Ltd	APOZINE SYRUP	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
473	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	MTI Medical Pvt Ltd	CYTO 500 MG TABLET	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
474	81	Clarithromycin Suspension 125mg/5ml	MTI Medical Pvt Ltd	GROTIC 125 MG/5 ML SUSPENION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22: Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
475	81	Clarithromycin Suspension 125mg/5ml	MTI Medical Pvt Ltd	GROTIC 125MG/5ML SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
476	85	Clopidogrel Tablets 75 mg	MTI Medical Pvt Ltd	DRAGREL 75mg TABLET	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria. Clause no.3:Experience of the quoted item was not atleast one year from date of registration.		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
477	106	Dobutamine (hydrochloride) Injection 250mg/5ml	MTI Medical Pvt Ltd	TOBUJECT INJECTION 250 MG	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria. Clause no 2:The quoted item Dobutamine 250mg/20ml did not comply with advertised specification Dobutamine 250mg/5ml		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no 2: The quoted item Dobutamine 250mg/20ml did not comply with advertised specification Dobutamine 250mg/5ml; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
478	108	Dopamine (hydrochloride) Injection 200mg/5ml	MTI Medical Pvt Ltd	Dopacin 200mg Injection	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria. Clause no.2:Drug registration certifiicate for quoted pack size 1's for quoted item not attached.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.2: Drug registration certifiicate for quoted pack size 1's for quoted item not attached. Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
479	108	Dopamine (hydrochloride) Injection 200mg/5ml	MTI Medical Pvt Ltd	Dopacin 200mg Injection	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.)		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
480	120	Fluconazole Capsules 150mg	MTI Medical Pvt Ltd	GRIBOK CAPSULES	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
481	120	Fluconazole Capsules 150mg	MTI Medical Pvt Ltd	GRIBOK 150MG CAPSULE	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
482	138	Ibuprofen Susp. 100mg/5ml	MTI Medical Pvt Ltd	PRUFIE 100 MG/5 ML SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
483	138	Ibuprofen Susp. 100mg/5ml	MTI Medical Pvt Ltd	PRUFIE 100MG/5ML SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
484	138	Ibuprofen Susp. 100mg/5ml	MTI Medical Pvt Ltd	PRUFIE 100MG/5M L SUSPENS ION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
485	147	Iron iii Hydroxide Polymaltose Syrup	MTI Medical Pvt Ltd	TEMURIN SYRUP	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
486	147	Iron iii Hydroxide Polymaltose Syrup	MTI Medical Pvt Ltd	TEMURIN SYRUP	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
487	148	Iron Sucrose Injection 100mg/5ml	MTI Medical Pvt Ltd	TEMURIN-S INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
488	151	Ketamine 50mg/ml Injection	MTI Medical Pvt Ltd	ANTAMIN INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
489	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	MTI Medical Pvt Ltd	APHOLAC ORAL SOLUTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
490	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	MTI Medical Pvt Ltd	APHOLAC ORAL SOLUTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
491	154	Levofloxacin Tablet 250mg	MTI Medical Pvt Ltd	LOFAMIN 250 MG TABLET	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
492	170	Meropenem 1G Injection	MTI Medical Pvt Ltd	PINOMER 1 GM INJECTION	Not Qualified	Firm wise: Clause no.7,8,9,10,11,12,16,17:Undertaking of contract manufacturer not provided. Clause no.22 Notarized undertaking not attached. Clause no.12:Calibration/validation record of stability chambers of contract manufacturer not attached. Clause no 15: Building fitness certificate/layout plan of contract manufacturer not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.7,8,9,10,11,12,16,17: The firm provided requisite undertakings of contract manufacturer, which were accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. Clause no.12: The firm provided Calibration certificates of stability chambers of contract manufacturer, which were accepted. Clause no 15: The firm provided layout plan of contract manufacturer, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided requisite undertaking as prescribed in PQ document, which was accepted.
493	199	Omeprazole Capsule 20mg	MTI Medical Pvt Ltd	GOTEC 20 MG CAPSULE S	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
494	200	Omeprazole Injection 40mg	MTI Medical Pvt Ltd	GOTEC 40 MG INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
495	201	Ondansetron injection 4mg/2ml	MTI Medical Pvt Ltd	MONDES INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
496	208	Paracetamol Syrup/Susp 160mg /5ml or less.	MTI Medical Pvt Ltd	CELSUS ORAL SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no:Valid DRC not attached. Clause no.5 :Undertaking not in accordance with advertised criteria.		The firm did not contest for the quoted item.
497	208	Paracetamol Syrup/Susp 160mg /5ml or less.	MTI Medical Pvt Ltd	CELSIUS 120MG ORAL SUSPENSION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no:Valid DRC not attached. Clause no.5 :Undertaking not in accordance with advertised criteria.		The firm did not contest for the quoted item.
498	260	Tazobactum+Piperacillin Injection 250mg+2gm	MTI Medical Pvt Ltd	TAZOPRID E STERILE POWDER INJECTION 2.25 GM	Not Qualified	Firm wise: Clause no.7,8,9,10,11,12,16,17:Undertaking of contract manufacturer not provided. Clause no.22 Notarized undertaking not attached. Clause no.12:Calibration/validation record of stability chambers of contract manufacturer not attached. Clause no 15: Building fitness certificate/layout plan of contract manufacturer not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		Firmwise Clause no.7,8,9,10,11,12,16,17: The firm provided requisite undertakings of contract manufacturer, which were accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. Clause no.12: The firm provided Calibration certificates of stability chambers of contract manufacturer, which were accepted. Clause no 15: The firm provided layout plan of contract manufacturer, which was accepted. Itemwise Clause no.5: The firm provided requisite undertaking as prescribed in PQ document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
499	261	Tazobactum+Piperacillin Injection 500mg+4gm	MTI Medical Pvt Ltd	TAZOPRID E INJECTION	Not Qualified	Firm wise: Clause no.7,8,9,10,11,12,16,17:Undertaking of contract manufacturer not provided. Clause no.22 Notarized undertaking not attached. Clause no.12:Calibration/validation record of stability chambers of contract manufacturer not attached. Clause no 15: Building fitness certificate/layout plan of contract manufacturer not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		Firmwise Clause no.7,8,9,10,11,12,16,17: The firm provided requisite undertakings of contract manufacturer, which were accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. Clause no.12: The firm provided Calibration certificates of stability chambers of contract manufacturer, which were accepted. Clause no 15: The firm provided layout plan of contract manufacturer, which was accepted. Itemwise Clause no.5: The firm provided requisite undertaking as prescribed in PQ document, which was accepted.
500	268	Tramadol HCl Capsule/Tablet 50 mg	MTI Medical Pvt Ltd	BITRAMOL 50 MG CAPSULES	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
501	276	Vancomycin (HCl) Injection 500 mg	MTI Medical Pvt Ltd	VINVIN 500 MG INJECTION	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
502	284	Zinc Sulphate Syrup 20mg/5ml.	MTI Medical Pvt Ltd	ZINCKY SYRUP	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
503	284	Zinc Sulphate Syrup 20mg/5ml.	MTI Medical Pvt Ltd	ZINCKY SYRUP	Not Qualified	Firm wise: Clause no.17:Undertaking submitted not in accordance with advertised criteria. Clause no.22 Notarized undertaking not attached. Item wise: Clause no.5 :Undertaking not in accordance with advertised criteria.		<u>Firmwise</u> Clause no.17: The firm provided undertaking as prescribed in PQ Document, which was accepted. Clause no.22: The firm provided requisite undertaking on notarized stamp paper, which was accepted. <u>Itemwise</u> Clause no.5: The firm provided undertaking as prescribed in PQ Document, which was accepted.
504	51	Calcium Carbonate Tablets (equalent to 400-500mg elemental calcium)	munawar pharma (Pvt) Ltd	Ostocal D 3H	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	M/S Munawar Pharma Pvt Ltd Lahore declared not qualified. In this regard our grievance request is mentioned below in annotative form with reply of observations:- Sr. No Inq No Name of Medicines with remarks 1105 51 Calcium carbonate tablets eq to 400-500mg elemental calcium Remarks:- Clause no 2: Quoted item did not comply with advertised specification Clause no 6: Sample standard of quoted item (over 5%) from 01-01-2021 Reply It is submitted that our product Ostocal-D 3H contains Calcium Carbonate 500mg as elemental calcium and Vitamin D 125 IU. All the Multinational companies and National companies have calcium carbonate with vitamin D. None of reputed Company in Pakistan Manufactured Calcium Carbonate without Vitamin D. In the last year DGHS Punjab had prequalified all the Companies with the same specification. Copy of notification attached. Annex-I It is further added here that (8) eight batches of our product Calcium Carbonate 500mg as elemental calcium and Vitamin D 125 IU (Ostocal-D 3H) was declared Substandard by DTL Multan which were challenged by our Company. From 01-01-2021 to 30-06-2021, We have manufactured 175 batches and supplied to Govt Sector as well as Private Sector. According to the Manufactured batches the ratio of 5% is 8.75 batches. According to that ratio our sample substandard ratio is not over 5%. The copy of batch production history is attached herewith for ready reference. (Annex-II)	Mr. Imran Rathore, Sales Officer from M/s Munawar pharma (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 2: The basic advertised ingredient(s) are present in the formulation of the quoted brand. As the quoted specification meets the advertised specification, the committee accepted the grievance of the firm to the extent of this parameter. Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 175 batches were manufactured out of which 8 were declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
505	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	munawar pharma (Pvt) Ltd	Stazin	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification		The firm did not contest for the quoted item.
506	138	Ibuprofen Susp. 100mg/5ml	munawar pharma (Pvt) Ltd	Ibuprofen	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification		The firm did not contest for the quoted item.
507	208	Paracetamol Syrup/Susp 160mg /5ml or less.	munawar pharma (Pvt) Ltd	Munapol	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
508	3	Acyclovir Injection 250 mg	Nabiqasim Industries (Private) Limited	Hypovir	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration/validation certificate/record of functional stability chamber not attached <u>Itemwise</u> Clause no. 2: Experience of quoted item of manufacturer from date of registration is less than one year	We are pleased to enclose along with following documentation / information for review of the decision of Prequalification Technical Evaluation Committee:- Inq. No. Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of non-prequalifying Completion of Short-falls 4 Acyclovir Injection 500 mg Hypovir Injection 500mg 500mg Firmwise: Clause No. 12: Calibration/validation certificate/record of functional stability chamber not attached Calibration / validation Certification attached 16 Amlodipine Tablets 5 mg Amdipine Tablet 5mg 30 Firmwise: Clause No. 12: Calibration/validation certificate/record of functional stability chamber not attached Itemwise: Clause No.2:DRAP approval for Quoted pack size and renewal not attached Calibration / validation Certification attached Copy of letter No. F.9-1/2010-DDC(P), dated 14-09-2010 showing additional pack attached 17 Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp. Rexyl Syrup 32mg+8mg+30 mg+0.98mg/5ml 120ml Firmwise: Clause No. 12: Calibration/validation certificate/record of functional stability chamber not attached Itemwise: Clause No. 2: DRAP approval for Quoted pack size and renewal not attached Calibration / validation Certification attached Copy of Readable DRC Attached 34 Artemether + Lumefantrine Suspension 15 + 90 mg Susp. Fanart junior Dry suspension Dry Powder Susp. 15mg+90mg 60ml Firmwise: Clause No. 12: Calibration/validation certificate/record of functional stability chamber not attached Itemwise: Clause No. 2: DRC Renewal not attached Calibration / validation Certification attached Copy of renewal letter attached 37 Atenolol Tablet 50mg Normitab Tablet 50mg 28 Firmwise: Clause No. 12: Calibration/validation certificate/record of functional stability chamber not attached Itemwise: Clause No. 2: DRAP approval for Quoted Pack size and Renewal not attached Calibration / validation Certification attached Copy of letter No. F.9-13/2008-DDC(P) Vol 1, dated 12-11-2009 showing additional pack attached 38 Atorvastatin Tablets 20mg Descol Tablet 20mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC	The firm did not contest for the quoted item.
509	4	Acyclovir Injection 500 mg	Nabiqasim Industries (Private) Limited	Hypovir	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration/validation certificate/record of functional stability chamber not attached	Mr. from M/s Nabiqasim Industries (Private) Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.	
510	16	Amlodipine Tablets 5 mg	Nabiqasim Industries (Private) Limited	Amdipine	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration/validation certificate/record of functional stability chamber not attached <u>Itemwise</u> Clause no.2:DRAP approval for Quoted pack size and renewal not attached	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 30's Pack, which was accepted.	
511	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	Nabiqasim Industries (Private) Limited	Rexyl	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration/validation certificate/record of functional stability chamber not attached <u>Itemwise</u> Clause no.2:DRC unreadable	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.	
512	34	Artemether + Lumefantrine Suspension 15 + 90 mg Susp.	Nabiqasim Industries (Private) Limited	Fanart junior Dry suspension	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration/validation certificate/record of functional stability chamber not attached <u>Itemwise</u> Clause no.2:DRC Renewal not attached	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
518	57	Cefixime Capsule/Tablets 400mg	Nabiqasim Industries (Private) Limited	Cefexol	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	attached Copy of DRC attached. 68 Cetirizine Tablets 10mg Neset Tablet Tablet 10mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
519	58	Cefixime Suspension 100mg/5ml	Nabiqasim Industries (Private) Limited	Cefexol Suspension	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	attached. 70 Chloramphenicol Eye Drops 0.5% w/v Comycetin eye Eye Drop 0.5% 10ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 72 Chloroquine (Phosphate or sulfate) Syrup 200 mg / 5 ml Miniquine Syrup 200mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Valid DRC not attached Clause No.3:With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of DRC No. 002731, dated 31-08-1982 attached. Copy of DRC showing experience of 40 years attached 75 Chlorpheniramine maleate Syrup 2 mg / 5ml Allergyx syrup Syrup 2mg/5ml 120ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval Valid DRC not attached Calibration / validation Certification attached Copy of letter No. F.3-4/88-Price, dated 10-01-1990 showing additional pack attached Copy of DRC attached 77 Ciprofloxacin (Hydrochloride) Tablets 500 mg Bacip Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC Renewal not attached Calibration / validation	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
520	59	Cefixime Suspension 200mg/5ml	Nabiqasim Industries (Private) Limited	Cefexol	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	attached. 70 Chloramphenicol Eye Drops 0.5% w/v Comycetin eye Eye Drop 0.5% 10ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 72 Chloroquine (Phosphate or sulfate) Syrup 200 mg / 5 ml Miniquine Syrup 200mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Valid DRC not attached Clause No.3:With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of DRC No. 002731, dated 31-08-1982 attached. Copy of DRC showing experience of 40 years attached 75 Chlorpheniramine maleate Syrup 2 mg / 5ml Allergyx syrup Syrup 2mg/5ml 120ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval Valid DRC not attached Calibration / validation Certification attached Copy of letter No. F.3-4/88-Price, dated 10-01-1990 showing additional pack attached Copy of DRC attached 77 Ciprofloxacin (Hydrochloride) Tablets 500 mg Bacip Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC Renewal not attached Calibration / validation	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
521	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	Nabiqasim Industries (Private) Limited	Neset syrup	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC Renewal not attached	attached. 70 Chloramphenicol Eye Drops 0.5% w/v Comycetin eye Eye Drop 0.5% 10ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 72 Chloroquine (Phosphate or sulfate) Syrup 200 mg / 5 ml Miniquine Syrup 200mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Valid DRC not attached Clause No.3:With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of DRC No. 002731, dated 31-08-1982 attached. Copy of DRC showing experience of 40 years attached 75 Chlorpheniramine maleate Syrup 2 mg / 5ml Allergyx syrup Syrup 2mg/5ml 120ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval Valid DRC not attached Calibration / validation Certification attached Copy of letter No. F.3-4/88-Price, dated 10-01-1990 showing additional pack attached Copy of DRC attached 77 Ciprofloxacin (Hydrochloride) Tablets 500 mg Bacip Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC Renewal not attached Calibration / validation	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
522	68	Cetirizine Tablets 10mg	Nabiqasim Industries (Private) Limited	Neset Tablet	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached	attached. 70 Chloramphenicol Eye Drops 0.5% w/v Comycetin eye Eye Drop 0.5% 10ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 72 Chloroquine (Phosphate or sulfate) Syrup 200 mg / 5 ml Miniquine Syrup 200mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Valid DRC not attached Clause No.3:With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of DRC No. 002731, dated 31-08-1982 attached. Copy of DRC showing experience of 40 years attached 75 Chlorpheniramine maleate Syrup 2 mg / 5ml Allergyx syrup Syrup 2mg/5ml 120ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval Valid DRC not attached Calibration / validation Certification attached Copy of letter No. F.3-4/88-Price, dated 10-01-1990 showing additional pack attached Copy of DRC attached 77 Ciprofloxacin (Hydrochloride) Tablets 500 mg Bacip Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC Renewal not attached Calibration / validation	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
523	69	Chloramphenicol Ear Drops 1% w/v	Nabiqasim Industries (Private) Limited	Comycetin ear Drop	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> cluase no.2:Quoted item did not comply with Advertise specification as it contains lignocaine hydrochloride as additional ingredient.	Certification attached Copy of renewal letter attached 81 Clarithromycin Suspension 125mg/5ml Clarithro Dry Powder Susp. 125mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval for Quoted pack size DRC not attached Calibration / validation Certification attached Copy of letter additional pack size and valid DRC attached 82 Clarithromycin Tablets 500mg Clarithro Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 85 Clopidogrel Tablets 75 mg Deplat Tablet 75mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 86 Clotrimazole Skin cream 1% w/w Dermosporin Cream 1% 20gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 87 Clotrimazole Vaginal Cream 10% Gynosporin Cream 10% 5gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Clause no.3: With reference to clause no. 2, one year experience of quoted item not fulfilled	The firm did not contest for the quoted item.
524	70	Chloramphenicol Eye Drops 0.5% w/v	Nabiqasim Industries (Private) Limited	Comycetin eye	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	81 Clarithromycin Suspension 125mg/5ml Clarithro Dry Powder Susp. 125mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval for Quoted pack size DRC not attached Calibration / validation Certification attached Copy of letter additional pack size and valid DRC attached 82 Clarithromycin Tablets 500mg Clarithro Tablet 500mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Calibration / validation Certification attached 85 Clopidogrel Tablets 75 mg Deplat Tablet 75mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 86 Clotrimazole Skin cream 1% w/w Dermosporin Cream 1% 20gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 87 Clotrimazole Vaginal Cream 10% Gynosporin Cream 10% 5gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Clause no.3: With reference to clause no. 2, one year experience of quoted item not fulfilled	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
525	72	Chloroquine (Phosphate or sulfate) Syrup 200 mg / 5 ml	Nabiqasim Industries (Private) Limited	Miniquine	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled	81 Clarithromycin Suspension 125mg/5ml Clarithro Dry Powder Susp. 125mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval for Quoted pack size DRC not attached Calibration / validation Certification attached 85 Clopidogrel Tablets 75 mg Deplat Tablet 75mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 86 Clotrimazole Skin cream 1% w/w Dermosporin Cream 1% 20gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 87 Clotrimazole Vaginal Cream 10% Gynosporin Cream 10% 5gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Clause no.3: With reference to clause no. 2, one year experience of quoted item not fulfilled	Firmwise Clause no.12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The quoted specification did not comply with advertised specification; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.3: With refrence to clause no.2,one year experience of quoted item not fulfilled
526	75	Chlorpheniramine maleate Syrup 2 mg / 5ml	Nabiqasim Industries (Private) Limited	Allergyx syrup	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRAP approval for Quoted pack size DRC not attacehd	81 Clarithromycin Suspension 125mg/5ml Clarithro Dry Powder Susp. 125mg/5ml 60ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval for Quoted pack size DRC not attached Calibration / validation Certification attached 85 Clopidogrel Tablets 75 mg Deplat Tablet 75mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 86 Clotrimazole Skin cream 1% w/w Dermosporin Cream 1% 20gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC unreadable Calibration / validation Certification attached Copy of readable DRC attached 87 Clotrimazole Vaginal Cream 10% Gynosporin Cream 10% 5gm Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Clause no.3: With reference to clause no. 2, one year experience of quoted item not fulfilled	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided DRAP approval of 120ml Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
527	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Nabiqasim Industries (Private) Limited	Bacip	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC Renewal not attached	20 Firmwise: Clause No.12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRAP approval for quoted pack DRC and renewal not attached Calibration / validation Certification attached Copy of letter for additional pack size attached Copy of DRC renewal attached 120 Fluconazole Capsules 150mg Fluderm Capsule 150mg Capsule Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal letter attached 121 Folic Acid Tablets 5mg Folitab Tablet 5mg 100 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 126 Glimepiride Tablets 2mg Norlim Tablet 2mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 160 Losartan Potassium Tablet 50mg Bepsar Tablet 50mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 182 Misoprostol Tablets 200mcg Tecmiso Tablet 200mcg 10 Firmwise: Clause No. 12: Minimum two	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
528	81	Clarithromycin Suspension 125mg/5ml	Nabiqasim Industries (Private) Limited	Clarithro	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRAP approval for Quoted pack size DRC not attached	Clarithromycin Suspension 125mg/5ml Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal letter attached 121 Folic Acid Tablets 5mg Folitab Tablet 5mg 100 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 126 Glimepiride Tablets 2mg Norlim Tablet 2mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 160 Losartan Potassium Tablet 50mg Bepsar Tablet 50mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 182 Misoprostol Tablets 200mcg Tecmiso Tablet 200mcg 10 Firmwise: Clause No. 12: Minimum two	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided DRAP approval of 60ml Pack, which was accepted.
529	82	Clarithromycin Tablets 500mg	Nabiqasim Industries (Private) Limited	Clarithro	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	Clarithromycin Tablets 500mg Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 126 Glimepiride Tablets 2mg Norlim Tablet 2mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 160 Losartan Potassium Tablet 50mg Bepsar Tablet 50mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 182 Misoprostol Tablets 200mcg Tecmiso Tablet 200mcg 10 Firmwise: Clause No. 12: Minimum two	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
530	85	Clopidogrel Tablets 75 mg	Nabiqasim Industries (Private) Limited	Deplat	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC unreadable	Clopidogrel Tablets 75 mg Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 154 Levofloxacin Tablet 250mg warrior Tablet 250mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 160 Losartan Potassium Tablet 50mg Bepsar Tablet 50mg 20 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 182 Misoprostol Tablets 200mcg Tecmiso Tablet 200mcg 10 Firmwise: Clause No. 12: Minimum two	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
531	86	Clotrimazole Skin cream 1% w/w	Nabiqasim Industries (Private) Limited	Dermosporin	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC unreadable	Clotrimazole Skin cream 1% w/w Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 182 Misoprostol Tablets 200mcg Tecmiso Tablet 200mcg 10 Firmwise: Clause No. 12: Minimum two	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
532	87	Clotrimazole Vaginal Cream 10%	Nabiqasim Industries (Private) Limited	Gynosporin	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled	Clause no.12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 184 Montelukast 4mg Dry Powder sachet Lungair Satche 4mg 14 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: Renewal DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached 185 Montelukast Tablets 10 mg Lungair Tablet 10mg 14 Firmwise: Clause No.12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC renewal attached	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.3: The experience of quoted item of manufacturer from date of registration is more than 1 year; hence, grievance of the firm was accepted to the extent of this parameter.
533	88	Clotrimazole Vaginal tablet 500 mg	Nabiqasim Industries (Private) Limited	Gynosporin	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached	Clause No.12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No.2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of DRC renewal attached Copy of DRC No. 035645, dated 31-12-2004 attached 198 Ofloxacin 200mg Tablets Albact Tablet 200mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC attached 199 Omeprazole Capsule 20mg Loprot Capsule 20mg 14 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC No. attached 200 Omeprazole Injection 40mg Loprot Injection 40mg 1's Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC No. attached 202 ORS Sachet (WHO Formulation) Normolyte Satche 3.5g+2.9g+1.5g +20g 20 Firm wise: Clause No. 12: Minimum two calibrated/validated	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted.
534	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Nabiqasim Industries (Private) Limited	Lisodim	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRAP approval forquoted pack size not attached Clause no.3: Experience is less than one year	dated 31-12-2004 attached 198 Ofloxacin 200mg Tablets Albact Tablet 200mg 10 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC attached 199 Omeprazole Capsule 20mg Loprot Capsule 20mg 14 Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC No. attached 200 Omeprazole Injection 40mg Loprot Injection 40mg 1's Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC No. attached 202 ORS Sachet (WHO Formulation) Normolyte Satche 3.5g+2.9g+1.5g +20g 20 Firm wise: Clause No. 12: Minimum two calibrated/validated	The firm did not contest for the quoted item.
535	118	Escitalopram Tablets 10mg	Nabiqasim Industries (Private) Limited	Es-pramcit	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRAP approval for quoted pack DRC and renewal not attached	attached Copy of DRC No. attached 200 Omeprazole Injection 40mg Loprot Injection 40mg 1's Firmwise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Itemwise: Clause No. 2: DRC not attached Calibration / validation Certification attached Copy of DRC No. attached 202 ORS Sachet (WHO Formulation) Normolyte Satche 3.5g+2.9g+1.5g +20g 20 Firm wise: Clause No. 12: Minimum two calibrated/validated	Firmwise Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. Itemwise Clause no.2: The firm provided DRAP approval of 20's Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
536	120	Fluconazole Capsules 150mg	Nabiqasim Industries (Private) Limited	Fluderm	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached	functional stability chamber certificate not attached Item wise: Clause No. 2: DRAP approval for Quoted pack size and renewal DRC not attached Calibration / validation Certification attached Due to typographical mistake we offered pack size of 14's instead of 20's kindly revalidate which valid drug registration attached 209 Paracetamol Tablet 500 mg Reliefal Tablet 500mg 200 Firm wise: Clause No.12: Minimum two calibrated/validated functional stability chamber certificate not attached Item wise: Clause No. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Calibration / validation Certification attached We have applied for dosage form of "Tablets Paracetamol (Reliefal)", whereas not a single batch declared /substandard by any DTL's of Punjab. 213 Permethrin Cream 5% Scabex Cream 50mg 30gm Firm wise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Item wise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
537	121	Folic Acid Tablets 5mg	Nabiqasim Industries (Private) Limited	Folitab	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached	functional stability chamber certificate not attached Item wise: Clause No. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Calibration / validation Certification attached We have applied for dosage form of "Tablets Paracetamol (Reliefal)", whereas not a single batch declared /substandard by any DTL's of Punjab. 213 Permethrin Cream 5% Scabex Cream 50mg 30gm Firm wise: Clause No. 12: Minimum two calibrated/validated functional stability chamber certificate not attached Item wise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
538	126	Glimepiride Tablets 2mg	Nabiqasim Industries (Private) Limited	Norlim	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached	functional stability chamber certificate not attached Item wise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
539	154	Levofloxacin Tablet 250mg	Nabiqasim Industries (Private) Limited	warrior	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached	functional stability chamber certificate not attached Item wise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
540	160	Losartan Potassium Tablet 50mg	Nabiqasim Industries (Private) Limited	Bepsar	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached	functional stability chamber certificate not attached Item wise: Clause No. 2: DRC not attached Clause No.3: With reference to Clause No. 2, one year experience of quoted item not fulfilled Calibration / validation Certification attached Copy of	<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
541	182	Misoprostol Tablets 200mcg	Nabiqasim Industries (Private) Limited	Tecmiso	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
542	184	Montelukast 4mg Dry Powder sachet	Nabiqasim Industries (Private) Limited	Lungair	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
543	185	Montelukast Tablets 10 mg	Nabiqasim Industries (Private) Limited	Lungair	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.3: The experience of quoted item of manufacturer from date of registration is more than 1 year; hence, grievance of the firm was accepted to the extent of this parameter.
544	198	Ofloxacin 200mg Tablets	Nabiqasim Industries (Private) Limited	Albact	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
545	199	Omeprazole Capsule 20mg	Nabiqasim Industries (Private) Limited	Loprot	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
546	200	Omeprazole Injection 40mg	Nabiqasim Industries (Private) Limited	Loprot	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
547	202	ORS Sachet (WHO Formulation)	Nabiqasim Industries (Private) Limited	Normolyte	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRAP approval for Quoted pack size and renewal DRC not attached		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 20's Pack, which was accepted.
548	209	Paracetamol Tablet 500 mg	Nabiqasim Industries (Private) Limited	Reliefal	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021); hence, grievance of the firm was not accepted to the extent of this parameter.
549	213	Permethrin Cream 5%	Nabiqasim Industries (Private) Limited	Scabex	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.3: The experience of quoted item of manufacturer from date of registration is more than 1 year; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
550	249	Sitagliptin 50mg Tablet	Nabiqasim Industries (Private) Limited	Glytec	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
551	276	Vancomycin (HCl) Injection 500 mg	Nabiqasim Industries (Private) Limited	Vanbact	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.3: The experience of quoted item of manufacturer from date of registration is more than 1 year; hence, grievance of the firm was accepted to the extent of this parameter.
552	283	Zinc Sulphate Dispersible Tablet 20 mg	Nabiqasim Industries (Private) Limited	Zynq Tab	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 8 batches were manufactured out of which none declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
553	284	Zinc Sulphate Syrup 20mg/5ml.	Nabiqasim Industries (Private) Limited	Zynq syrup	Not Qualified	<u>Firmwise</u> Clause no.12:Minimum two calibrated/validated functional stability chamber certificate not attached <u>Itemwise</u> Clause no.2: Renewal DRC not attached Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no.12: The firm provided calibration certificates of functional stability chamber, which were accepted. <u>Itemwise</u> Clause no.2: Renewal DRC not attached Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 60 batches were manufactured out of which none declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.
554	10	Amikacin (Sulphate) Injection 100mg	Neutro Pharma(Pvt) Ltd	Amikaneu	Not Qualified	<u>Firmwise</u> Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired <u>Itemwise</u> Clause no.1: Quoted item section not prequalified Clause no.2:DRC renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached	M/S Neutro Pharma (Pvt) Ltd was declared not qualified due to following reasons. Firm Wise: 1- ISO 9001, 45001, 14001 Expired . 2- GMP Expired. Item Wise: 1- Quoted Item Section not Prequalified. 2- DRC Renewals not attached. 3- Undertaking for Clause 7 Daily Production Capacity of each quoted item not attached. 4- Undertaking for Clause 8 Maximum Batch Size of each quoted product not attached. Explanation: Firm wise: Sir we have attached valid ISO Certificates for ISO 19001, 45001 and 14001. (ANNEX-A) Valid GMP report is attached that was under process in DRAP. (ANNEX-B) Item Wise: GMP report is attached for quoted item section verification. DRC Renewals are attached. (ANNEX-C) Undertaking for Clause 7 (Daily Production capacity for each quoted product) and Clause 8 (Maximum Batch Size for each quoted product) separately on Notarized Stamp papers. (ANNEX-D)	Mr. Zohaib Maqsood, Assisntant Manager Quality Assurance from M/s Neutro Pharma (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted. <u>Itemwise</u> Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
555	11	Amikacin (Sulphate) Injection 250mg	Neuro Pharma(Pvt) Ltd	amikaneu	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
556	41	Azithromycin Capsules/Tab 250mg	Neuro Pharma(Pvt) Ltd	Aziro capsule	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
557	42	Azithromycin Capsules/Tab 500mg	Neuro Pharma(Pvt) Ltd	Aziro 500 mg	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRAP approval for quoted pack size and DRC renewal not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
558	58	Cefixime Suspension 100mg/5ml	Neuro Pharma(Pvt) Ltd	Serve suspension	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
559	59	Cefixime Suspension 200mg/5ml	Neutro Pharma(Pvt) Ltd	Serve suspension	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired and no section for dry powder suspension Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 28 batches were manufactured out of which 1 was declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
560	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Neuro Pharma(Pvt) Ltd	vexa 1 g	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
561	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Neuro Pharma(Pvt) Ltd	Vexa 250 mg	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
562	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Neuro Pharma(Pvt) Ltd	vexa 500 mg	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
563	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Neuro Pharma(Pvt) Ltd	Affif tablet	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
564	81	Clarithromycin Suspension 125mg/5ml	Neuro Pharma(Pvt) Ltd	Claromy suspension	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired and no section for dry powder suspension Clause no.2:DRC Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
565	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Neuro Pharma(Pvt) Ltd	Heumatic injection	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
566	107	Domperidone 10mg Tablet	Neuro Pharma(Pvt) Ltd	Domact tablet	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRAP approval for quoted pack size and Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided DRAP approval of 50's Pack instead of 30's; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
567	110	Drotaverine 40mg/2ml Injection	Neuro Pharma(Pvt) Ltd	Spracid injection	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC renewal; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
568	148	Iron Sucrose Injection 100mg/5ml	Neuro Pharma(Pvt) Ltd	Neufer Injection	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC for quoted pack size and Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided DRAP approval of 5's Pack, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
569	154	Levofloxacin Tablet 250mg	Neuro Pharma(Pvt) Ltd	Lefoxin tablet	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
570	193	Normal Saline Infusion 0.9% 100ml	Neutro Pharma(Pvt) Ltd	Neusold infusion	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>
571	198	Ofloxacin 200mg Tablets	Neutro Pharma(Pvt) Ltd	Bacrid tablet	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:Valid DRC not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided valid DRC of quoted item, which was accepted. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
572	199	Omeprazole Capsule 20mg	Neutro Pharma(Pvt) Ltd	Omenext capsule	Not Qualified	<p>Firmwise</p> <p>Clause no.3:GMP Expired Clause no.4:ISO 9001 Expired Clause no.5:ISO 14001 Expired Clause no.6:ISO 18001 Expired</p> <p>Itemwise</p> <p>Clause no.1:Prequalification of quoted item section is expired Clause no.2:DRC Renewal not attached Clause no.7:Undertaking for Daily production capacity of each quoted item not attached Clause no.8:Undertaking for Maximum batch size of quoted item not attached</p>		<p><u>Firmwise</u></p> <p>Clause no.3: The provided valid GMP certificate, which was accepted. Clause no.4: The provided ISO 9001, which was accepted. Clause no.5: The provided ISO 18001, which was accepted. Clause no.6: The provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.1: Quoted item section on GMP is prequalified; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.2: The firm provided DRC renewal of quoted item; hence, grievance of the firm was accepted to the extent of this parameter. Clause no.7: The provided undertaking for Daily production capacity of quoted item, which was accepted. Clause no.8: The provided undertaking for Maximum batch size of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
573	57	Cefixime Capsule/Tablets 400mg	News Pharma	New-Xime capsule	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than Rs.550 millions</p> <p>Clause no15:Building fitness certificate not atatched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurious/adulterated not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>	<p>We are submitting again documents prequalification related documents detail following below. 1. Undertaking Regarding blacklisting/Debarring 2. GMP Certificate, Inspection Report 3. Quality Certificate(ISO 9001) 4. Environmental Certificate 5. Undertaking equipment installed in quality control lab for analysis for all quoted items 6. Undertaking separate quality control and biological lab 7. Undertaking equipment installed in quality control lab for analysis for all quoted items available and functional and not deficient to perform official tests of the (quoted) product 8. Undertaking functional and validated, Heating, Ventilation & Air Conditioning System (HVAC) 9. Undertaking R.O Water/De-ionized water Plant 10. Undertaking two functional stability chambers 11. Undertaking Annexure A 12. Income Tax Return (FY 2020-21) 13. Building Fitness Certificate 14. Undertaking follows the labor laws (Including child free labor and minimum wages as per Government policy). 15. Undertaking its manufactured batch sample has been declared Spurious/Adulterated since Last 3 years onward. 16. SOP's regarding drug recall 17. Any Conviction by Drug Court against firm (PQCB) 18. Undertaking Accept all terms and condition So we are humbly request to you please consider our grievance application and do qualified our firm.</p>	<p>No representative from M/s News Pharma attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report.</p> <p>The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
574	58	Cefixime Suspension 100mg/5ml	News Pharma	New-Xime 100mg/5ml	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
575	59	Cefixime Suspension 200mg/5ml	News Pharma	New-Xime DS	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
576	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	News Pharma	New-Zone	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
577	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	News Pharma	New-Zone	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
578	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	News Pharma	New-Zone 500mg	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
579	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	News Pharma	Newsfenac	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
580	104	Dimenhydrinate 50mg/ml injection	News Pharma	New-Nate	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
581	124	Gentamycin Injection 80mg	News Pharma	Gentamicin	Not Qualified	<p><u>Firmwise</u></p> <p>Clause no.2:undertaking for blaclisting not attached</p> <p>Clause no.3:GMP expired</p> <p>Clause no.4:valid ISO 9001 not attached</p> <p>Clause no.5:valid ISO 14001 not attached</p> <p>Clause no.6: 18001 not attached</p> <p>Clause no.7:Undertaking for equipment installed not attached</p> <p>Clause no.8:Undertaking for separate Quality control and microbiological lab not attached</p> <p>Clause no.9:Undertaking for equipment installed for analysis not attached</p> <p>Clause no.10:Undertaing for facility having HVAC not attached</p> <p>Clause no.11:Undertaking for R.O water not attached</p> <p>Clause no.12:Undertaking for Stability chamber and Certificates not attached</p> <p>Clause no.13:Undertaking for information provided by firms is not attched</p> <p>clause no.14:minimum financial turnover is less than550 millions</p> <p>Clause no15:Building fitness certificate not attched</p> <p>Clause no.16:Undertaking for labor laws not attached</p> <p>Clause no.17:Undertaking for spurios/adultered not attached</p> <p>Clause no .18:SOP for recall not attached</p> <p>Clause no.20:Undertaking fpr prosecution by PQCB not attached</p> <p>Clause no22:Undetaking for applicant accepts all terms and condition not attached</p> <p><u>Itemwise</u></p>		<p><u>Firmwise</u></p> <p>Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted.</p> <p>Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
582	173	Metoclopramide (hydrochloride) Injection 10mg	News Pharma	Newmide	Not Qualified	"Firmwise, Clause no.2:undertaking for blaclisting not attached Clause no.3:GMP expired Clause no.4:valid ISO 9001 not attached Clause no.5:valid ISO 14001 not attached Clause no.6: 18001 not attached Clause no.7:Undertaking for equipment installed not attached Clause no.8:Undertaking for separate Quality control and microbiological lab not attached Clause no.9:Undertaking for equipment installed for analysis not attached Clause no.10:Undertaing for facility having HVAC not attached Clause no.11:Undertaking for R.O water not attached Clause no.12:Undertaking for Stability chamber and Certificates not attached Clause no.13:Undertaking for information provided by firms is not attched clause no.14:minimum financial turnover is less than550 millions Clause no15:Building fitness certificate not attched Clause no.16:Undertaking for labor laws not attached Clause no.17:Undertaking for spurios/adultered not attached Clause no .18:SOP for recall not attached Clause no.20:Undertaking fpr prosecution by PQCB not attached Clause no22:Undetaking for applicant accepts all terms and condition not attached Itemwise		<u>Firmwise</u> Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted. Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter. clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
583	279	Vitamin D3 Injection 5mg	News Pharma	New-D	Not Qualified	"Firmwise, Clause no.2:undertaking for blaclisting not attached Clause no.3:GMP expired Clause no.4:valid ISO 9001 not attached Clause no.5:valid ISO 14001 not attached Clause no.6: 18001 not attached Clause no.7:Undertaking for equipment installed not attached Clause no.8:Undertaking for separate Quality control and microbiological lab not attached Clause no.9:Undertaking for equipment installed for analysis not attached Clause no.10:Undertaing for facility having HVAC not attached Clause no.11:Undertaking for R.O water not attached Clause no.12:Undertaking for Stability chamber and Certificates not attached Clause no.13:Undertaking for information provided by firms is not attched clause no.14:minimum financial turnover is less than550 millions Clause no15:Building fitness certificate not attched Clause no.16:Undertaking for labor laws not attached Clause no.17:Undertaking for spurios/adultered not attached Clause no .18:SOP for recall not attached Clause no.20:Undertaking fpr prosecution by PQCB not attached Clause no22:Undetaking for applicant accepts all terms and condition not attached Itemwise		<u>Firmwise</u> Clause no.2: The firm did not provide original undertaking for blaclisting; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.4: The firm did not provide valid ISO 9001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.6: The firm did not provide valid ISO 18001/45001 with (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) / United Kingdom Accreditation Service (UKAS)/ International Accreditation Forum (IAF) / International Accreditation Service (IAS); hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.5: The provided ISO 18001; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.7: The firm did not provide original undertaking for equipment installed; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.8: The firm did not provide original undertaking for separate Quality control and microbiological lab; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.9: The firm did not provide original undertaking for equipment installed for analysis, which was accepted. Clause no.10: The firm did not provide original undertaing for facility having HVAC not attached; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.11: The firm did not provide original undertaking for R.O water; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.12: The firm did not provide original undertaking for Stability chamber along with calibration certificate; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.13: The firm did not provide original undertaking for information provided by firms; hence, grievance of the firm was not accepted to the extent of this parameter. clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/201920/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
584	34	Artemether + Lumefantrine Suspension 15 + 90 mg Susp.	Opal Laboratories (Pvt.)Ltd.	Malther Dry Suspension	Not Qualified	<u>Itemwise</u> Clause no.2:DRC not attached	Our 03 quoted products are not qualified due to following reason. 1) Z-Mac Suspension & Z-Mac Capsule is not qualified due to non-submission of valid Renewal of both products 2) Malther Dry Suspension.is not qualified due to non submission of Drug Registration Certificate and Renewal of the product. Therefore, the valid Renewal letter of our quoted products (Z-Mac Dry Suspension & Z-Mac Capsule) is attached for your kind consideration. Further; Drug Registration Letter and Renewal letter of our quoted product (Malther Dry Suspension) is attached for your kind consideration	Mr. Danish Naqvi, Sales Manager from M/s Opal Laboratories (Pvt.)Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
585	41	Azithromycin Capsules/Tab 250mg	Opal Laboratories (Pvt.)Ltd.	Z-Mac Capsule	Not Qualified	<u>Itemwise</u> Clause no.2:DRC expired		<u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
586	43	Azithromycin Susp 200mg/5ml	Opal Laboratories (Pvt.)Ltd.	Z-Mac Suspension	Not Qualified	<u>Itemwise</u> Clause no.2:DRC expired		<u>Itemwise</u> Clause no.2: The firm provided valid DRC of quoted item, which was accepted.
587	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	PDH Pharmaceuticals (Pvt)Ltd	Vindril Syrup	Not Qualified	<u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attched moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached	Please find attached herewith documents as directed by you, we hope you would find these documents in order, meantime we assure you our best of attention, we remain.	Mr. Muhammad Ahmad, Senior Business Officer from M/s PDH Pharmaceuticals (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
588	51	Calcium Carbonate Tablets (equivalent to 400-500mg elemental calcium)	PDH Pharmaceuticals(Pvt)Ltd	Calcium-P Tabs	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statement not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adulterated not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no. 2: Quoted item did not comply with Advertise specification as it contains Vitamin D as additional ingredient Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>		<p><u>Firmwise</u> Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adulterated, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p><u>Itemwise</u> Clause no. 2: The basic advertised ingredient(s) are present in the formulation of the quoted brand. As the quoted specification meets the advertised specification, the committee accepted the grievance of the firm to the extent of this parameter. Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021); hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
589	53	Calcium phosphate 210mg/5ml or above	PDH Pharmaceutical s(Pvt)Ltd	Calcium-P Susp	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no. 2: Quoted item did not comply with Advertise specification as it contains Vitamin D as additional ingredient Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>		<p><u>Firmwise</u> Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p><u>Itemwise</u> Clause no. 2: Quoted item did not comply with Advertise specification as it contains Vitamin D as additional ingredient Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021); hence, grievance of the firm was not accepted to the extent of this parameter.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
590	57	Cefixime Capsule/Tablets 400mg	PDH Pharmaceuticals(Pvt)Ltd	Ceflorex Caps 400mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>
591	58	Cefixime Suspension 100mg/5ml	PDH Pharmaceuticals(Pvt)Ltd	Ceflorex Susp 100mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
592	59	Cefixime Suspension 200mg/5ml	PDH Pharmaceuticals(Pvt)Ltd	Ceflorex Susp DS 200mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attched Clause no.14:Financial turnover for 2020-2021 and bank statment not attched moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no.2:DRC expired</p>		<p><u>Firmwise</u> Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p><u>Itemwise</u> Clause no.2:DRC expired</p>
593	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	PDH Pharmaceuticals(Pvt)Ltd	Cezine Syrup	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attched Clause no.14:Financial turnover for 2020-2021 and bank statment not attched moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no.2:DRC expired</p>		<p><u>Firmwise</u> Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p><u>Itemwise</u> Clause no.2:DRC expired</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
594	68	Cetirizine Tablets 10mg	PDH Pharmaceuticals(Pvt)Ltd	Cezine Tabs 10mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>
595	75	Chlorpheniramine maleate Syrup 2 mg / 5ml	PDH Pharmaceuticals(Pvt)Ltd	Allerphene Syrup	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no.2:DRC Not attached Clause no.3:With refrence to clause no.2,one year experience of quoted item not fulfilled</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p>Itemwise Clause no.2: DRC Not attached Clause no.3: With refrence to clause no.2,one year experience of quoted item not fulfilled</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
596	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	PDH Pharmaceuticals(Pvt)Ltd	Kuin Tabs	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>
597	154	Levofloxacin Tablet 250mg	PDH Pharmaceuticals(Pvt)Ltd	Quest Tabs 250mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
598	160	Losartan Potassium Tablet 50mg	PDH Pharmaceuticals(Pvt)Ltd	Giozar Tabs 50mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>
599	185	Montelukast Tablets 10 mg	PDH Pharmaceuticals(Pvt)Ltd	Montana Tabs 10mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attached Clause no.14:Financial turnover for 2020-2021 and bank statment not attached moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
600	198	Ofloxacin 200mg Tablets	PDH Pharmaceuticals(Pvt)Ltd	Floxol Tabs 200mg	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attched Clause no.14:Financial turnover for 2020-2021 and bank statment not attched moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p> <p><u>Itemwise</u> Clause no.2:DRC expired</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p> <p>Itemwise Clause no.2:DRC expired</p>
601	245	Salbutamol Syrup	PDH Pharmaceuticals(Pvt)Ltd	Butamin Syrup	Not Qualified	<p><u>Firmwise</u> Clause no.3,4&5:ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12:two calibrated/validated stability chambers certificate not attched Clause no.14:Financial turnover for 2020-2021 and bank statment not attched moreover minimum annual turnover is less than 550 million for FY 2018-19&2019-20 Clause no.17:Undertaking for Spurious and adultered not attached Clause no.20:Undertaking for prosecuted by PQCB not attached</p>		<p>Firmwise Clause no.3, 4 & 5: ISO 9001,14001&18001 not approved from PNAC/UKAS/IAF/IAS Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted Clause no.14: Minimum Annual financial turnover for any of single financial year (i.e. 2018-19/2019-20/2020-21)/calendar year (i.e. 2018/2019/2020) is less than 550 Million Rupees; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no.17: The firm provided undertaking for Spurious and adultered, which was accepted. Clause no.20: The firm provided undertaking for prosecuted by PQCB, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
602	41	Azithromycin Capsules/Tab 250mg	Pfizer Pakistan Limited	Zetamax Capsule	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached Itemwise Clause no.2: DRAP approval of quoted pack not attached.	We hereby take this opportunity to submit our clarifications and documents to fulfill the deficiencies. The point wise and product wise details and submissions are under: A. Firm wise Criteria – Local manufacturer Observation: Clause 12: Calibration/validation documents of stability chamber not attached. Submission: We hereby submit the missing “valid calibration/validation certificates” of the stability chambers. Annex-A. Observation: Clause 14: Income Tax/Sales tax return for the financial year 2020-2021 not attached. Clarification: The Accounting year for our company is from December to November this is also special Tax Year. We have submitted the following returns: Accounting Year Tax Year From to Submission Date/Due date 2019 01-12-2017 30-Nov-2018 30-09-2019 2020 01-12-2018 30-Nov-2019 30-09-2020 2021 01-12-2019 30-Nov-2020 30-09-2021 Next return Due 2022 01-12-2020 30-Nov-2021 30-09-2022 (To be submitted) Our last submitted return is that of for tax year 2021 and next return has not yet been submitted. Further, as far as the annual turnover Rs.550.00 Mio in any single year during the past 3 years is concerned, we fulfill this condition in all the years stated above. Copies of tax return attached. Annex-B B. Quoted Product/Item wise Criteria a. Inq. No. 41, Azithromycin 250mg Tab./Cap. (Zetamax 250 mg. Caps) Observation: DRAP approval of quoted pack size not attached. Clarification: We quoted pack size of 6's. Our original registration is for pack size of 6's. There is no change of pack size from registered pack to quoted pack. (Copy of Reg. letter attached. Annex-C b. Inq. No. 166, Medroxyprogesterone acetate inj. 150mg/ml. (Depo Provera In. 150mg/ml.) Observation: Valid Sole Agency Agreement not attached. Clarification: Sole agency agreement / authority letter attached. Annex-D c. Inq No. 167, Mefenamic Acid Tab. 500 mg. (Ponstan Forte Tablets 500 mg.) Observation: DRAP approval of quoted pack size not attached. Clarification: DRAP notification on price fixation	Mr. Muzzamil Chaudhry, Distributor of M/s Pfizer Pakistan Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted. <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 6's Pack, which was accepted.
603	42	Azithromycin Capsules/Tab 500mg	Pfizer Pakistan Limited	Zetamax tablet	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached	Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.	
604	43	Azithromycin Susp 200mg/5ml	Pfizer Pakistan Limited	zetamax suspension	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached	Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.	
605	109	Doxycycline (hyclate) Capsules 100mg	Pfizer Pakistan Limited	Vibramycin Capsule	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached	Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
606	166	Medroxyprogesterone acetate Inj. 150mg/ml	Pfizer Pakistan Limited	Depo Provera Inj 150mg/mL	Not Qualified	Firmwise Clause no. 3: Undertaking for blacklisting not attached Clause no. 14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached Itemwise Clause no. 8: Valid sole agency agreement not attached	showing Ponstan Forte 500 mg. Tablets pack of 200's is attached. Annex-E. d. Meningococcal conjugate vaccine (Nimenrix Vaccine) Observation: Clause 3. Undertaking for blacklisting not attached. Clarification: We already attached the said undertaking with our original application. However, we hereby attach the same again for your consideration. Annex-F. We hope to have clarified the observations and fulfilled the deficiencies to your satisfaction.	Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted. Itemwise Clause no. 8: The firm provided valid sole agency agreement, which was accepted.
607	167	Mefenamic acid Tablet 500 mg	Pfizer Pakistan Limited	Ponstan Forte Tablets	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached Itemwise Clause no.2: DRAP approval of quoted pack not attached.		Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted. Itemwise Clause no.2: The firm provided DRAP approval of 200's Pack, which was accepted.
608	169	Meningococcal conjugate vaccine (WHO Prequalified)	Pfizer Pakistan Limited	Nimenrix Vaccine	Not Qualified	Firmwise Clause no. 3: Undertaking for blacklisting not attached		Firmwise Clause no. 3: The firm provided undertaking for blacklisting, which was accepted.
609	229	Prednisolone Tablets 5mg	Pfizer Pakistan Limited	Deltacortil 5mg Tablet	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached		Firmwise Clause no.12: The firm provided calibration certificates of stability chamber, which was accepted. Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.
610	235	Rifampicin+Isoniazid (RH 150+75) Tablets(Bioavailability/ Bioequivalence study must be attached along with bid and study must be available on WHO Website)	Pfizer Pakistan Limited	Rin Tablets	Not Qualified	Firmwise Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached		Firmwise Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
611	236	Rifampicin+Isoniazid +Ethambutol (RHE 150+75+275) Tablets (Bioavailability/Bioequivalence study must be attached along with bid and study must be available on WHO Website)	Pfizer Pakistan Limited	Myrin Forte Tablet	Not Qualified	Firmwise Clause no.12: Calibrated/validated stability chamber certificate not attached Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached Itemwise The Bioequivalence/bioavaibility study not attached as per advertise specification		The firm did not contest for the quoted item.
612	237	Rifampicin+Isoniazid +Pyrazinamide+Ethambutol (RHZE 150+75+400+275) tablets (Bioavailability/Bioequivalence study must be attached along with bid and study must be available on WHO Website)	Pfizer Pakistan Limited	Myrin P fORTE	Not Qualified	Firmwise Clause no.14: Income Tax/Sales Tax return for the financial year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Income Tax/Sales Tax return for the financial year 2020-2021, which was accepted.
613	39	Atracurium (besylate) Injection 10mg/ml	Pharmasol (Private) Ltd	Tardax 10mg Injection	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached	All of our products were disqualified because of cluase 14 (complete bank statement not attached) We are hereby attaching complete bank statements for your ready reference with tax returns in soft and submitting the same in hard.	Mr. Awais Akhtar, Senior Account from M/s Pharmasol (Private) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
614	41	Azithromycin Capsules/Tab 250mg	Pharmasol (Private) Ltd	Zithrocin Capsule 250mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
615	42	Azithromycin Capsules/Tab 500mg	Pharmasol (Private) Ltd	Zithrocin 500mg Tablet	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
616	43	Azithromycin Susp 200mg/5ml	Pharmasol (Private) Ltd	"Zithrocin Suspension "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
617	57	Cefixime Capsule/Tablets 400mg	Pharmasol (Private) Ltd	"Axoral Capsule 400mg "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
618	58	Cefixime Suspension 100mg/5ml	Pharmasol (Private) Ltd	"Axoral Dry Suspension 100mg/5ml "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
619	59	Cefixime Suspension 200mg/5ml	Pharmasol (Private) Ltd	"Axoral DS Dry Suspension 200mg/5ml "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
620	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Pharmasol (Private) Ltd	"TXR Dry Powder Injection 1g (IV) "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
621	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Pharmasol (Private) Ltd	"TXR Dry Powder Injection 500mg (IV) "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
622	79	Ciprofloxacin Eye Drops 0.3% w/v	Pharmasol (Private) Ltd	Ciproxol Eye Drops	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
623	81	Clarithromycin Suspension 125mg/5ml	Pharmasol (Private) Ltd	"Selclar Suspension 125mg/5ml "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
624	82	Clarithromycin Tablets 500mg	Pharmasol (Private) Ltd	Selclar Tablets 500mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
625	85	Clopidogrel Tablets 75 mg	Pharmasol (Private) Ltd	"Clopisel Tablet "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
626	107	Domperidone 10mg Tablet	Pharmasol (Private) Ltd	Seldom Tablet 10mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
627	118	Escitalopram Tablets 10mg	Pharmasol (Private) Ltd	Selpram Tablet 10MG	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.
628	120	Fluconazole Capsules 150mg	Pharmasol (Private) Ltd	Konacane Capsule 150mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
629	134	Hydrocortisone (Sodium succinate) Injection 100mg	Pharmasol (Private) Ltd	Hicartif Dry Powder Injection 100mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
630	135	Hydrocortisone (Sodium succinate) Injection 250mg	Pharmasol (Private) Ltd	Hicartif Dry Powder Injection 250mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
631	147	Iron iii Hydroxide Polymaltose Syrup	Pharmasol (Private) Ltd	"Fertonic Syrup "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
632	170	Meropenem 1G Injection	Pharmasol (Private) Ltd	"Merosol Injection IV 1g "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
633	184	Montelukast 4mg Dry Powder sachet	Pharmasol (Private) Ltd	Montisel 4mg Sachet	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
634	185	Montelukast Tablets 10 mg	Pharmasol (Private) Ltd	Montisel Tablet	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
635	186	Moxifloxacin Eye drops 0.5%(5ml)	Pharmasol (Private) Ltd	Moxol Ophthalmic Solution	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
636	188	Nalbuphine Hcl Injection 10mg/ml	Pharmasol (Private) Ltd	Nalbusol 10mg/ml Injection	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
637	201	Ondansetron injection 4mg/2ml	Pharmasol (Private) Ltd	"Deston Injection "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
638	214	Permethrin Lotion 5%	Pharmasol (Private) Ltd	Methrix Lotion	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
639	248	Silver Sulphadiazine Cream 1%	Pharmasol (Private) Ltd	"Silverex Cream 1% w/w "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
640	267	Tobramycin + Dexamethasone Eye Drops	Pharmasol (Private) Ltd	Tobracort Ophthalmic Suspension	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
641	268	Tramadol HCl Capsule/Tablet 50 mg	Pharmasol (Private) Ltd	Tramax Capsule 50mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
642	269	Tramadol HCl Injection 100mg/2ml	Pharmasol (Private) Ltd	"Tramax Injection 100mg "	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
643	270	Tranexamic Acid Capsules 500mg	Pharmasol (Private) Ltd	Inxamic 500mg Capsules	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
644	271	Tranexamic Acid Injection 500mg/5ml	Pharmasol (Private) Ltd	Inxamic 500mg/5ml Injection	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
645	276	Vancomycin (HCl) Injection 500 mg	Pharmasol (Private) Ltd	Vancosol for Injection 500mg	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
646	281	Water for injection 10 ml Sterile	Pharmasol (Private) Ltd	PSOL WFI 10ML	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
647	282	Water for injection 5 ml Sterile	Pharmasol (Private) Ltd	PSOL WFI 5ML	Not Qualified	<u>Firmwise</u> Clause no.14:Complete Bank statment for financial Year 2020-2021 not attached		<u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial Year 2020-2021, which was accepted.
648	16	Amlodipine Tablets 5 mg	PHARMATEC PAKISTAN (PVT.) LTD.	AMLOCAR D 5 TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.	FIRM WISE:- Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached. We are forwarding herewith the undertaking on Rs.100 stamp paper dully legalized/notarized that we have separate Quality Control and Microbiological labs. ITEM WISE:- Item S/N: 1304 & Inq. No. 245 (Salbutamol Syrup):- Clause no.2: DRAP approval of quoted pack of 120ml not attached. We are forwarding herewith the DRAP approved letter for approval of additional pack size of 120ml. Therefore, we are submitting herewith the aforesaid missing documents along with this grievance application	Mr. Muhammad Ikram, Senior Field Manager from M/s Pharmatec attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
649	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	PHARMATEC PAKISTAN (PVT.) LTD.	RELTUS EXP SYRUP	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached. <u>Itemwise</u> Clause no.2: Quoted specification does not comply with Advertised specification.		The firm did not contest for the quoted item.
650	38	Atorvastatin Tablets 20mg	PHARMATEC PAKISTAN (PVT.) LTD.	ATORVA 20MG TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
651	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	PHARMATEC PAKISTAN (PVT.) LTD.	ALERID SYRUP	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
652	68	Cetirizine Tablets 10mg	PHARMATEC PAKISTAN (PVT.) LTD.	ALERID TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
653	94	Dextromethorphan + Diphenhydramine/C PM/Pseudoephedrine+ others ingredients as antitussive/dry cough Syrup/Susp.	PHARMATEC PAKISTAN (PVT.) LTD.	RELTUS DM SYRUP 120ML	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
654	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	PHARMATEC PAKISTAN (PVT.) LTD.	LONAC 50 TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
655	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	PHARMATEC PAKISTAN (PVT.) LTD.	LONAC INJECTION S	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
656	154	Levofloxacin Tablet 250mg	PHARMATEC PAKISTAN (PVT.) LTD.	LEFLOTEC 250MG TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
657	167	Mefenamic acid Tablet 500 mg	PHARMATEC PAKISTAN (PVT.) LTD.	ZOPAN DS 500MG TABLET	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
658	185	Montelukast Tablets 10 mg	PHARMATEC PAKISTAN (PVT.) LTD.	MONTEC 10MG TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
659	199	Omeprazole Capsule 20mg	PHARMATEC PAKISTAN (PVT.) LTD.	PRAZOL CAPSULE S	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
660	244	Salbutamol (Sulfate) Tablets 4mg	PHARMATEC PAKISTAN (PVT.) LTD.	VENEX 4 TABLETS	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
661	245	Salbutamol Syrup	PHARMATEC PAKISTAN (PVT.) LTD.	VENEX SYRUP 120ml	Not Qualified	<u>Firmwise</u> Clause no.8:Undertaking for separate Quality control and microbiological lab not attached <u>Itemwise</u> Clause no.2: DRAP approval of quoted pack of 120ml not attached		<u>Firmwise</u> Clause no.8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted. <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 120ml Pack, which was accepted.
662	249	Sitagliptin 50mg Tablet	PHARMATEC PAKISTAN (PVT.) LTD.	Galsit 50mg Tablets	Not Qualified	<u>Firmwise</u> Clause no.8:Undertaking for separate Quality control and microbiological lab not attached		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
663	279	Vitamin D3 Injection 5mg	PHARMATEC PAKISTAN (PVT.) LTD.	CHOLTEC INJECTION	Not Qualified	<u>Firmwise</u> Clause no. 8: Undertaking for separate Quality control and microbiological lab not attached.		<u>Firmwise</u> Clause no. 8: The firm provided undertaking for separate Quality control and microbiological lab, which was accepted.
664	59	Cefixime Suspension 200mg/5ml	PharmEvo (Pvt) Ltd.	Evofix DS Susp	Not Qualified	<u>Itemwise</u> Clause no.2: Firm did not quote volume of Evofix DS suspension in the PQ application cover sheet/PQOD	We have been declared as not prequalified in following items due to reasons mentioned:- 1. Inquiry No. 59 Evofix Suspension 200mg/5ml Clause no.2: Firm did not quote volume of Evofix DS suspension in the PQ application cover sheet/PQOD Answer: We have quote Evofix Suspension 200mg/5ml quoted volume 30ml.We have only 30ml volume approval by DRAP.We have filled this volume of 30ml as approved by DRAP but unfortunately due to error it could not be appear in online portal.Keeping in view of above it is requested to consider our quoted volume as per DRAP approval i.e. 30ml and declared us as	Mr. Abdul Hafeez, Senior Area Manager from M/s PharmEvo (Pvt) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no.2: The firm provided DRAP approval of 30ml Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
665	184	Montelukast 4mg Dry Powder sachet	PharmEvo (Pvt) Ltd.	Aireez 4mg Sachet	Not Qualified	<p><u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)</p>	<p>as per DCA approval i.e. 50ml and declared us as prequalified. 2. Inquiry No. 184 Aireez 4mg Sachet Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021) Answer: It is submitted that there is no batch of Aireez 4mg Sachet reported to us declared substandard by DTL. Pre-qualification Evaluation committee may be confused it with other item/firms. It is requested to recheck the data and declared us prequalified for this item as there is no</p>	<p><u>Itemwise</u> Clause no. 6: The firm provided record of batch manufactured by the firm of the quoted item during the stipulated period. 3 batches were manufactured out of which zero declared substandard, therefore, percentage of batches declared substandard was less than 5%. ; hence, grievance of the firm was accepted to the extent of this parameter.</p>
666	68	Cetirizine Tablets 10mg	Pulse Pharmaceuticals (Pvt.) Ltd.	Tryzin 10mg Tablet	Not Qualified	<p><u>Firmwise</u> Clause no.14:Bank statment for financial year 2020-2021 not attached Clause no.15:Building fitness certificate not attached Clause no.20:Undertaking was not notorized Clause no.22:Undertaking was not notorized <u>Itemwise</u> Clause no.6:Undertaking not attached Clause no.7:Undertaking was not notorized Clause no.8:Undertaking was not notorized</p>	<p>It is informed to you that the following are the reasons for not prequalified products 1. Clause No 14. Bank Statement for Financial Year 2020-2021 is attached. 2. Clause No 15. Building fitness Certificate and Lay out Plan are attached. 3. Clause No 20. Notarized Undertaking is attached. 4. Clause No 22. Notarized undertaking item wise is attached. 5. Clause No 6. Notarized undertaking is attached. 6. Clause No 7. Notarized undertaking is attached. 7. Clause No 8. Notarized undertaking is attached.</p>	<p>Mr. Muhammad Usman, Manager Institutional from M/s Pulse Pharmaceuticals (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.14: The firm provided Bank statment for financial year 2020-2021, which was accepted. Clause no.15:Building fitness certificate, which was accepted. Clause no.20 & 22: The firm provided requisite undertakings on notorized stamp paper, which was accepted. <u>Itemwise</u> Clause no.6, 7 & 8: The firm provided requisite undertakings on notorized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
667	88	Clotrimazole Vaginal tablet 500 mg	Pulse Pharmaceuticals (Pvt.) Ltd.	Pulsetine Vaginal 500mg Tablet	Not Qualified	Firmwise Clause no.14:Bank statment for financial year 2020-2021 not attached Clause no.15:Building fitness certificate not attached Clause no.20:Undertaking was not notorized Clause no.22:Undertaking was not notorized Itemwise Clause no.6:Undertaking not attached Clause no.7:Undertaking was not notorized Clause no.8:Undertaking was not notorized		Firmwise Clause no.14: The firm provided Bank statment for financial year 2020-2021, which was accepted. Clause no.15:Building fitness certificate, which was accepted. Clause no.20 & 22: The firm provided requisite undertakings on notorized stamp paper, which was accepted. Itemwise Clause no.6, 7 & 8: The firm provided requisite undertakings on notorized stamp paper, which was accepted.
668	120	Fluconazole Capsules 150mg	Pulse Pharmaceuticals (Pvt.) Ltd.	Pulcon 150mg Capsule	Not Qualified	Firmwise Clause no.14:Bank statment for financial year 2020-2021 not attached Clause no.15:Building fitness certificate not attached Clause no.20:Undertaking was not notorized Clause no.22:Undertaking was not notorized Itemwise Clause no.6:Undertaking not attached Clause no.7:Undertaking was not notorized Clause no.8:Undertaking was not notorized		Firmwise Clause no.14: The firm provided Bank statment for financial year 2020-2021, which was accepted. Clause no.15:Building fitness certificate, which was accepted. Clause no.20 & 22: The firm provided requisite undertakings on notorized stamp paper, which was accepted. Itemwise Clause no.6, 7 & 8: The firm provided requisite undertakings on notorized stamp paper, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
669	154	Levofloxacin Tablet 250mg	Pulse Pharmaceuticals (Pvt.) Ltd.	Lexof 250mg Tablet	Not Qualified	<p>Firmwise</p> <p>Clause no.14:Bank statment for financial year 2020-2021 not attached</p> <p>Clause no.15:Building fitness certificate not attached</p> <p>Clause no.20:Undertaking was not notorized</p> <p>Clause no.22:Undertaking was not notorized</p> <p>Itemwise</p> <p>Clause no.6:Undertaking not attached</p> <p>Clause no.7:Undertaking was not notorized</p> <p>Clause no.8:Undertaking was not notorized</p>		<p>Firmwise</p> <p>Clause no.14: The firm provided Bank statment for financial year 2020-2021, which was accepted.</p> <p>Clause no.15:Building fitness certificate, which was accepted.</p> <p>Clause no.20 & 22: The firm provided requisite undertakings on notorized stamp paper, which was accepted.</p> <p>Itemwise</p> <p>Clause no.6, 7 & 8: The firm provided requisite undertakings on notorized stamp paper, which was accepted.</p>
670	199	Omeprazole Capsule 20mg	Pulse Pharmaceuticals (Pvt.) Ltd.	Healer 20mg Capsule	Not Qualified	<p>Firmwise</p> <p>Clause no.14:Bank statment for financial year 2020-2021 not attached</p> <p>Clause no.15:Building fitness certificate not attached</p> <p>Clause no.20:Undertaking was not notorized</p> <p>Clause no.22:Undertaking was not notorized</p> <p>Itemwise</p> <p>Clause no.6:Undertaking not attached</p> <p>Clause no.7:Undertaking was not notorized</p> <p>Clause no.8:Undertaking was not notorized</p>		<p>Firmwise</p> <p>Clause no.14: The firm provided Bank statment for financial year 2020-2021, which was accepted.</p> <p>Clause no.15:Building fitness certificate, which was accepted.</p> <p>Clause no.20 & 22: The firm provided requisite undertakings on notorized stamp paper, which was accepted.</p> <p>Itemwise</p> <p>Clause no.6, 7 & 8: The firm provided requisite undertakings on notorized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
671	117	Erythropoietin 4000-5000 I.U Injection Vial/Pre-filled syringe	Roche Pakistan Limited	Recormon 5000IU PFS/0.3ml PFS	Not Qualified	<u>Firmwise</u> Clause no. 5: Undertaking that the information provided by the firm is in accordance with terms & conditions of prequalification documents not attached	The reported deficiencies and our submissions point-by-point are as under: A: FIRM WISE KNOCK DOWN CRITERIA Observation: Clause no. 5: Undertaking that the information provided by the firm is in accordance with terms & conditions of prequalification documents not attached Reply: Undertaking submitted in hard copy are legalized / notarized by the Notary Public copy of undertaking attached for reference. You are kindly requested to please accept our attached documents to settle your observation on our application and our company at its quoted product may kindly be declared as "Prequalified".	Mr. Usama Baig, Sales Executive of M/s Roche Pakistan Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 5: The firm provided undertaking that the information provided by the firm is in accordance with terms & conditions of prequalification documents, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
672	117	Erythropoietin 4000-5000 I.U Injection Vial/Pre-filled syringe	SAMI Pharmaceuticals (Pvt.) Limited	ROPO 4000 IU Injection	Not Qualified	<p>Firmwise</p> <p>Clause no.8: Undertaking for separate QC and microbiological lab not attached</p> <p>Clause no.10: Undertaking for functional and validated HVAC not as per advertise PQ documents</p> <p>Clause no.17: Undertaking for spurious and adulterated in public sector not as per advertise PQ documents</p> <p>Itemwise</p> <p>Clause no.5: Undertaking for spurious and adulterated sample not attached</p> <p>Clause no.6: Sample substand not over 5% not attached</p> <p>Clause no.8: Undertaking for maximum batch size not as per advertise documents</p> <p>Clause no.11: Undertaking for Punitive action taken by PQCB not as per advertise documents</p>	<p>This is with reference to the captioned subject and referred evaluation report for the year 2022-2023 Our product mentioned at S.No.1353 with item code 117 was declared "Not Qualified", hence we would like to humbly submit our grievance to your competent authority as follows and in accordance with the requirements raised by the department: S.No Reason/ Comments mentioned in Report Our Submission at time of opening Submission/ Comments Firm wise 1</p> <p>Clause no.8: Undertaking for separate QC and microbiological lab not attached We have already submitted the requisite undertaking dully notarized at the time of prequalification dully enclosed in file mentioned at S.No. 10 (viii) and enclosed at page no.170 , snap shot of the online portal at time of online submission is also being attached herewith for your kind perusal We however would like to submit the requisite undertaking once again for your kind perusal 2</p> <p>Clause no.10: Undertaking for functional and validated HVAC not as per advertise PQ documents We have already submitted the requisite undertaking dully notarized at the time of prequalification dully enclosed in file mentioned at S.No. 10 (x) and enclosed at page no.917 We however would like to submit the requisite undertaking once again on fresh format as desired for your kind perusal 3</p> <p>Clause no.17: Undertaking for spurious and adulterated in public sector not as per advertise PQ documents We have already submitted the requisite undertaking dully notarized at the time of prequalification dully enclosed in file mentioned at S.No. 10 (xvii) and enclosed at page no.1030 We however would like to submit the requisite undertaking once again on fresh format as desired for your kind perusal</p> <p>Item wise 1</p> <p>Clause no.5: Undertaking for spurious and adulterated sample not attached We have already submitted the requisite</p>	<p>Mr. Abid Ali, National Sales Manager from M/s SAMI Pharmaceuticals (Pvt.) Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report.</p> <p>The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u></p> <p>Clause no.8: The firm provided undertaking for separate QC and microbiological lab, which was accepted.</p> <p>Clause no.10: The firm provided undertaking for functional and validated HVAC, which was accepted.</p> <p>Clause no.17: The firm provided undertaking for spurious and adulterated in public sector, which was accepted.</p> <p><u>Itemwise</u></p> <p>Clause no.5: The firm provided undertaking for spurious and adulterated sample, which was accepted.</p> <p>Clause no.6: The firm provided undertaking Sample substandard not over 5%, which was accepted.</p> <p>Clause no.8: The firm provided undertaking for maximum batch size, which was accepted.</p> <p>Clause no.11: The firm provided undertaking for Punitive action taken by PQCB, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
673	126	Glimepiride Tablets 2mg	Sanofi-aventis pakistan limited	AMARYL TABLET 2mg 2x15	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP Approval of quoted pack size not attached.	As per evaluation report your evaluation committee declare our quoted items no. 126 Glimepiride Tablets 2mg (Amaryl Tab 2mg), 176 Metronidazole (Benzoate) Syrup 200 mg / 5ml (FLAGYL SUSPENSION 200mg/5ml 120ml), 176 Metronidazole (Benzoate) Syrup 200 mg / 5ml (FLAGYL SUSPENSION 200mg/5ml 90ml) and 231 Promethazine (HCL) Syrup/Elixir 5mg/5ml (PHENERGAN ELIXIR 120ml) non responsive due to DRAP Approval of quoted pack size not attached. Sir we are surprise to see that all our quoted items declared non responsive which are brands of Sanofi and we have all the valid and DRAP approvals, in our bid we attached the latest renewals of our quoted items which also indicate/mention the pack size of the products but for your satisfaction we are again submitting DRCs along with DRAP Approvals with our grievance letter. Furthermore, your evaluation committee also declare our quoted item no. 281 & 282 Water for injection 5ml & 10ml Sterile non responsive due to Renewal application for registration of quoted item not attached. Sir, our water for injections is specially manufactured by us, only for our product and we didn't sale it locally. We submitted our renewal request in DRAP before due date which is May 20,2016 and actual due date is Oct 29, 2018. DRAP issue PROVISIONAL LIST OF RENEWAL APPLICATIONS in which it clearly mentions that "Any application which is received within due date specified in the registration letter and also reflected in the list shall continue to be valid until orders are passed by the Registration Board in this behalf or till next date of renewal" (List Attach). According to the list and actual due date Oct 29, 2018, our submitted renewal is valid up to Oct 29, 2023.	Mr. Mohsin Hasan, Distributor of M/s Sanofi-aventis pakistan limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 30's Pack, which was accepted.
674	176	Metronidazole (Benzoate) Syrup 200 mg / 5ml	Sanofi-aventis pakistan limited	FLAGYL SUSPENSION 200mg/5ml 120ml	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP Approval of quoted pack size not attached.		<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 120ml Pack, which was accepted.
675	176	Metronidazole (Benzoate) Syrup 200 mg / 5ml	Sanofi-aventis pakistan limited	FLAGYL SUSPENSION 200mg/5ml 90ml	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP Approval of quoted pack size not attached.		<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 90ml Pack, which was accepted.
676	231	Promethazine (HCL) Syrup/Elixir 5mg/5ml	Sanofi-aventis pakistan limited	PHENERGAN ELIXIR 120ml	Not Qualified	<u>itemwise</u> Clause no. 2: DRAP Approval of quoted pack size not attached.		<u>itemwise</u> Clause no. 2: The firm provided DRAP approval of 120ml Pack, which was accepted.
677	281	Water for injection 10 ml Sterile	Sanofi-aventis pakistan limited	WATER FOR INJECTION 96x10ml	Not Qualified	<u>Itemwise</u> Clause no. 2: Renewal application for registration of quoted item not attached.		<u>Itemwise</u> Clause no. 2: The firm provided Renewal application for registration of quoted item, which was accepted.
678	282	Water for injection 5 ml Sterile	Sanofi-aventis pakistan limited	WATER FOR INJECTION 215x5ml	Not Qualified	<u>Itemwise</u> Clause no. 2: Renewal application for registration of quoted item not attached.		<u>Itemwise</u> Clause no. 2: The firm provided Renewal application for registration of quoted item, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
679	95	Dextrose 10% 1000ml	Shazeb Pharmaceutical Industries ltd	Zeesol-10%	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>	<p>Our products were declared as not-qualified on the following grounds: 1. Firm-wise: ISO 9001, 1400 & 45001 are not attached 2. Item wise: Daily Production capacity and maximum batch size of the quoted products on judicial stamp paper not attached</p> <p>Explanations 1. We had already attached the recommendation letter of the above-mentioned ISOs; we are attaching the copies of the required ISO Certificates for your consideration. 2. Moreover, we already had attached the stamp paper covering clauses 7 & 8 along with other clauses. However, we are attaching stamp papers for these clauses separately and item-wise for all the quoted items for the prequalification.</p>	<p>Mr. Muhammad Umair, Coordinator of M/s Shazeb Pharmaceutical Industries Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report.</p> <p>The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
680	96	Dextrose Infusion 5%, 1000ml)	Shazeb Pharmaceutical Industries ltd	Zeesol-5%	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
681	97	Dextrose Injection 25% (20ml/25ml) Ampoule	Shazeb Pharmaceutical Industries ltd	Dextrose 25% Inj	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
682	98	Dextrose+Saline (1000ml) Infusion 5%w/v +0.9%w/v	Shazeb Pharmaceutical Industries ltd	Zeesol-DS	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
683	142	Infusion 1/2 Normal Saline infusion 500 ml	Shazeb Pharmaceutical Industries ltd	Zeesol-1/2	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
684	162	Mannitol (500ml) Infusion 20% w/v	Shazeb Pharmaceutical Industries ltd	Zeesol-M	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
685	177	Metronidazole 500mg/100ml infusion	Shazeb Pharmaceutical Industries ltd	Zee-Met	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
686	192	Normal Saline Infusion 0.9% (1000ml)	Shazeb Pharmaceutical Industries ltd	Zeesol-NS	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
687	193	Normal Saline Infusion 0.9% 100ml	Shazeb Pharmaceutical Industries ltd	Zeesol-NS	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
688	210	Peads Soln Infusion 1/5 Normal Saline infusion (Paeds solution) 500 ml	Shazeb Pharmaceutical Industries ltd	Zeesol-Paeds	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
689	225	Potassium Chloride (KCL) Solution 7.46% in 20/25ml ampoule	Shazeb Pharmaceutical Industries ltd	Potassium Chloride Inj	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
690	239	Ringer's Lactate (1000ml) Infusion	Shazeb Pharmaceutical Industries ltd	Zeesol-H	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
691	240	Ringer's Lactate (500ml)	Shazeb Pharmaceutical Industries ltd	Zeesol-H	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>
692	250	Sodium Bicarbonate 8.4% w/v inj.	Shazeb Pharmaceutical Industries ltd	Zeelon-84	Not Qualified	<p><u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not atatched. Clause no.5: ISO 14001/EHS policy/ enviorment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
693	281	Water for injection 10 ml Sterile	Shazeb Pharmaceutical Industries ltd	Zeesol-Inject	Not Qualified	<u>Firmwise</u> Clause no. 4: ISO 9001/firm's quality management SOP not attached. Clause no.5: ISO 14001/EHS policy/ environment protection agency approval not attached. Clause no. 6: ISO 18001/45001 not attached. <u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximun batch size of quoted item on notarized stamp paper not attached.		<u>Firmwise</u> Clause no. 4: The firm provided ISO 9001, which was accepted. Clause no.5: The firm provided ISO 14001, which was accepted. Clause no. 6: The firm provided ISO 45001, which was accepted. <u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximun batch size of quoted item on notarized stamp paper, which was accepted.
694	112	DTP Vaccine WHO pre-qualified	Sind Medical Stores	DTP Vaccine	Not Qualified	<u>Itemwise</u> Clause no. 3: Experience of quoted item is less one year from date of registration	Attached documents from foreign principal for perusal and hope that you will understand and accept our grievance and prequalify our product based on following documents.	Mr. Malik Bashir Ahmad, Distributor of M/s Sind Medical Stores attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 3: The experience of quoted item is less one year from date of registration; hence, grievance of the firm was not accepted to the extent of this parameter.
695	6	Albendazole Susp. 200mg / 5ml	stanley pharmaceutical s (pvt) ltd	Bendazol Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.	We have been declared as not prequalified in following items due to reasons mentioned:- Firm Wise Clause: Clause no.12: Calibration certificates of stability chambers not attached. Answer: We have already attached calibration certificate of stability chamber in our PQ application and are attaching again for consideration. Item Wise Clause: Calsid Liquid:Clause no. 2: Quoted specification does not comply with advertised specification Answer: We 100% comply with advertised specification of quoted item. We have same specification as that of Qalsium D of GSK consumer health and GSK Pakistan, having additional important ingredient of vitamin D. Calcium and vitamin D are essential for each other and in all formulation of calcium vitamin D is added for efficient	Mr. Muzammil Iqbal, Sales Manager from M/s Stanley Pharmaceuticals (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
696	7	Albendazole Tablets 200mg	stanley pharmaceutical s (pvt) ltd	Bendazol Tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
697	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	stanley pharmaceuticals (pvt) ltd	Broxol Syrup	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.	absorption of calcium. Pedrol Suspension Clause no. 2: Approval of the quoted pack size (90ml) by DRAP not attached. Answer: We have already attached the approval for additional pack size of 90ml along with PQ application.	<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
698	30	Antacid suspension containing Magnesium Hydroxides, Aluminum Hydroxide including other relevant ingredients Susp.	stanley pharmaceuticals (pvt) ltd	Manacid Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
699	53	Calcium phosphate 210mg/5ml or above	stanley pharmaceuticals (pvt) ltd	Calsid Liquid	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted. <u>Itemwise</u> Clause no. 2: The basic advertised ingredient(s) are present in the formulation of the quoted brand. As the quoted specification meets the advertised specification, the committee accepted the grievance of the firm to the extent of this parameter.
700	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	stanley pharmaceuticals (pvt) ltd	Rozid 500mg Tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
701	94	Dextromethorphan + Diphenhydramine/C PM/Pseudoephedrine+ others ingredients as antitussive/dry cough Syrup/Susp.	stanley pharmaceuticals (pvt) ltd	Broxol DM	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.
702	103	Dimenhydrinate 50mg tab	stanley pharmaceuticals (pvt) ltd	Dymin Tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.	<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
703	105	Dimenhydrinate Suspension/Syrup 12.5mg/4ml	stanley pharmaceutical s (pvt) ltd	Dymin Syrup	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
704	105	Dimenhydrinate Suspension/Syrup 12.5mg/4ml	stanley pharmaceutical s (pvt) ltd	Dymin Syrup	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
705	107	Domperidone 10mg Tablet	stanley pharmaceutical s (pvt) ltd	Domtek Tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
706	109	Doxycycline (hyclate) Capsules 100mg	stanley pharmaceutical s (pvt) ltd	Ridox Capsule	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
707	119	Ferrous salt + Folic Acid Capsule/Tablets	stanley pharmaceutical s (pvt) ltd	Ferfolic Capsule	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
708	138	Ibuprofen Susp. 100mg/5ml	stanley pharmaceutical s (pvt) ltd	Fenbro Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
709	138	Ibuprofen Susp. 100mg/5ml	stanley pharmaceutical s (pvt) ltd	Fenbro Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
710	138	Ibuprofen Susp. 100mg/5ml	stanley pharmaceutical s (pvt) ltd	Fenbro Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
711	167	Mefenamic acid Tablet 500 mg	stanley pharmaceutical s (pvt) ltd	Kamic Forte	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
712	167	Mefenamic acid Tablet 500 mg	stanley pharmaceutical s (pvt) ltd	Kamic Forte tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
713	179	Metronidazole Tablets 400 mg	stanley pharmaceutical s (pvt) ltd	Riam Tablet	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
714	207	Paracetamol 80mg/0.8ml syrup/solution/drops	stanley pharmaceutical s (pvt) ltd	Pedrol Drops	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
715	207	Paracetamol 80mg/0.8ml syrup/solution/drops	stanley pharmaceutical s (pvt) ltd	Pedrol Drops	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		Firmwise Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
716	207	Paracetamol 80mg/0.8ml syrup/solution/drops	stanley pharmaceuticals (pvt) ltd	Pedrol Drops	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
717	208	Paracetamol Syrup/Susp 160mg /5ml or less.	stanley pharmaceuticals (pvt) ltd	Pedrol Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
718	208	Paracetamol Syrup/Susp 160mg /5ml or less.	stanley pharmaceuticals (pvt) ltd	Pedrol Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: Approval of the quoted pack size by DRAP not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted. <u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 90ml Pack, which was accepted.
719	208	Paracetamol Syrup/Susp 160mg /5ml or less.	stanley pharmaceuticals (pvt) ltd	Pedrol Suspension	Not Qualified	<u>Firmwise</u> Clause no.12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no.12: The firm provided calibration certificate of stability chambers, which were accepted.
720	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	Star Laboratories PVT LTD	Bronil Syrup	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.	cGMP Certificate is not fault of the company, inspection is delayed at DRAP end. DRAP inspection reports attached for approval of section.	Mr. Muhammad Afzaal, Manager Sales from M/s Star Laboratories Pvt Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
721	34	Artemether + Lumefantrine Suspension 15 + 90 mg Susp.	Star Laboratories PVT LTD	Artemax Plus Suspension	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
722	57	Cefixime Capsule/Tablets 400mg	Star Laboratories PVT LTD	Reyan Capsule	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
723	58	Cefixime Suspension 100mg/5ml	Star Laboratories PVT LTD	Reyan Oral Suspension	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
724	59	Cefixime Suspension 200mg/5ml	Star Laboratories PVT LTD	Reyan DS Suspension	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
725	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Star Laboratories PVT LTD	Rocetrax - 100 Injection I.V	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate. Clause no. 2: Quoted specification does not comply with advertised specification		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate. Clause no. 2: Quoted specification does not comply with advertised specification
726	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Star Laboratories PVT LTD	Rocetrax - 25 Injection I.V	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
727	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Star Laboratories PVT LTD	Rocetrax-50 Injection I.V	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
728	64	Cephradine Capsule 500mg	Star Laboratories PVT LTD	Stardin Capsule	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
729	65	Cephradine Injection 500mg	Star Laboratories PVT LTD	Stardin - 500 Injection	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
730	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Star Laboratories PVT LTD	Starcip 500mg Tablet	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
731	81	Clarithromycin Suspension 125mg/5ml	Star Laboratories PVT LTD	Clarista Suspension	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
732	82	Clarithromycin Tablets 500mg	Star Laboratories PVT LTD	Clarista Tablet 500mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
733	103	Dimenhydrinate 50mg tab	Star Laboratories PVT LTD	Emetox Tablet	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
734	109	Doxycycline (hyclate) Capsules 100mg	Star Laboratories PVT LTD	Infadox Capsules	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
735	154	Levofloxacin Tablet 250mg	Star Laboratories PVT LTD	Staflox Tablet 250mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
736	176	Metronidazole (Benzoate) Syrup 200 mg / 5ml	Star Laboratories PVT LTD	Nidagyl Suspension	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
737	178	Metronidazole Tablets 200 mg	Star Laboratories PVT LTD	Nidagyl Tablet 200mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
738	179	Metronidazole Tablets 400 mg	Star Laboratories PVT LTD	Nidagyl Tablet 400mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
739	185	Montelukast Tablets 10 mg	Star Laboratories PVT LTD	Montel Tablet 10mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
740	199	Omeprazole Capsule 20mg	Star Laboratories PVT LTD	Segazole Capsule 20mg	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.
741	209	Paracetamol Tablet 500 mg	Star Laboratories PVT LTD	Residol Tablet	Not Qualified	<u>Firmwise</u> Clause no. 3: GMP certificate expired. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.		<u>Firmwise</u> Clause no. 3: The firm did not provide valid GMP certificate or valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. <u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
742	10	Amikacin (Sulphate) Injection 100mg	Surge Laboratories Private Limited.	Prekacin	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>	<p>We would like to inform you that we applied our 25 Drugs / Medicines for Prequalification with the Director General Health Services, Punjab, Lahore / Secretary, Government of the Punjab, Primary & Secondary Healthcare Department, Lahore by providing / enclosing therewith all the pre-requisites for the purpose. It has been noticed through the above referred Prequalification Evaluation Report that our all the 25 items have not been qualified on the basis of non-submission of documentation. We are pleased to enclose along with following documentation to review the decision of Prequalification Technical Evaluation Committee:- Inq. No. Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of non-prequalifying Completion of Short-falls 10 Amikacin (Sulphate) Injection 100mg Prekacin Injection 100mg/2ml 1's Firm wise Clause No. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause No. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause No. 17 Injection CLOTIDE declared spurious vide TRA No.01-139001386 dated: 08-08-2019. Item wise Clause No. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause No. 8: Daily production capacity of quoted item not attached. Undertakings on Stamp Papers of Rs.100 duly notarized are attached. Building Fitness Certificate of Manufacturing Site on Form-K attached. One Batch No. CLI-060A of Clotide 10mg/2ml</p>	<p>Mr. Asim Raza, National Sales Manager from M/s Surge Laboratories Private Limited. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter. Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
743	11	Amikacin (Sulphate) Injection 250mg	Surge Laboratories Private Limited.	Prekacine	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>	<p>Injection was declared Spurious by DTL, Lahore while same batch was declared as of standard quality thrice by DTL, Lahore (Details given in the end of letter) Undertakings on Stamp Papers of Rs.100 duly notarized are attached. Affidavit on Stamp Papers of Rs.100 of Daily production is Attached. 11 Amikacin (Sulphate) Injection 250mg Prekacine Injection 250mg/2ml 1's 39 Atracurium (besylate) Injection 10mg/ml Efacurim Injection 50mg/5ml 5's 40 Atropine (Sulfate) injection 1mg/ml Atroject Injection 1mg/1ml 100's 49 Bupivacaine (hydrochloride) (spinal) Injection 0.75% (Amp of 2 ml) Nervlok Injection 7.5mg/ml, Ampoule of 2ml 10's 52 Calcium Gluconate Injection 100 mg/ml Calcium Gluconate Injection 1g/10ml 10's 60 Ceftriaxone (Sodium) Injection 1gm (I.V) Sergifex Injection 1gm 1's 61 Ceftriaxone (Sodium) Injection 250mg (I.V) Sergifex Injection 250mg 1's 62 Ceftriaxone (Sodium) Injection 500 mg (I.V) Sergifex Injection 500mg 1's 65 Cephadrine Injection 500mg Brocef Injection 500mg 1's 80 Ciprofloxacin Infusion 200mg / 100ml Bacip IV Infusion 200mg/100ml 1's 101 Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule Lisodim Injection 75mg/3ml 100's 124 Gentamycin Injection 80mg Genxat Injection 80mg/2ml 50's 146 Ipratropium Bromide Nebulizing Solution Ventpro Nebuliser Solution for Inhalation 500mcg/2ml 6's 148 Iron Sucrose Injection 100mg/5ml Megafer Injection 100mg/5ml 5's 156 Lignocaine (hydrochloride) 2% Injection Lidoject Injection 200mg/10ml 50's 177 Metronidazole 500mg/100ml infusion Intobix IV Infusion 500mg/100ml 1's 193 Normal Saline Infusion 0.9% 100ml Celine Infusion 0.9% 100ml 206 Paracetamol 1gm/100ml Infusion FEVERAL IV Infusion 1gm/100ml 100ml 259 Suxamethonium (chloride) Injection 100mg/2ml Neuronium Injection 100mg/2ml 5's 269 Tramadol HCl Injection 100mg/2ml Trompol Injection 100mg/2ml 5's 271 Tranexamic Acid Injection 500mg/5ml Tranmax Injection 500mg/5ml 10's 279 Vitamin D3 Injection 5mg Trick-D Injection 5mg/1ml</p>	<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
744	39	Atracurium (besylate) Injection 10mg/ml	Surge Laboratories Private Limited.	Efacurim	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>	<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance to the Firm	Decision by the Committee
745	40	Atropine (Sulfate) injection 1mg/ml	Surge Laboratories Private Limited.	Atroject Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>	<p>1ml 281 Water for injection 10 ml Sterile Water For Injection 10ml 50's 282 Water for injection 5 ml Sterile Water For Injection 5ml 100's Brief History against Clause # 17. We had supplied a bulk part of this product namely, Clotide inj. Batch No.CLI-060A to the Services Hospital, Lahore. The respective Drug Inspector had taken a sample from the stock for test/analysis and sent to the DTL, Lahore. The test/analysis report of the sample was generated dated 11/05/2019.The sample was declared of Standard Quality. (Copy Attached) Again another sample of the product namely, Clotide Injection Batch No.CLI-060A was taken by the Drug Inspector Services Hospital , Lahore from the stocks for test/analysis and sent to DTL, Lahore .The test analysis report of this sample was generated dated 23/08/2019. The sample was declared of Standard Quality again. (Copy Attached) On 02/08/2019 Mr. Munawar the learned Chief Drug Controller, along with Provincial Drug inspector Sheikhpura Mr. Imran visited our manufacturing plant. The officers sealed the samples of Injection Clotide Batch No.CLI-060A, for test /analysis by DTL/Government Analyst, again for the third time the sample was declare of Standard Quality by DTL Punjab dated 16-09-2019. (Copy Attached) The case was taken up by the PQCB, discussed and deliberated at length in its various meeting. However in view of the other three reports of the same batch of the Clotid injection, whereby it was found to be of Standard Quality and that we were not manufacturing the product reported in the impugned test/ analysis report, the report for the sample taken Lady Aitchsion Hospital was not established as correct and factual.</p>	<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
746	49	Bupivacaine (hydrochloride) (spinal) Injection 0.75% (Amp of 2 ml)	Surge Laboratories Private Limited.	Nervlok	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>	<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
747	52	Calcium Gluconate Injection 100 mg/ml	Surge Laboratories Private Limited.	Calcium Gluconate	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
748	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Surge Laboratories Private Limited.	Sergifex Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
749	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Surge Laboratories Private Limited.	Sergifex Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
750	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Surge Laboratories Private Limited.	Sergifex Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
751	65	Cephradine Injection 500mg	Surge Laboratories Private Limited.	Brocef Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
752	80	Ciprofloxacin Injection 200mg / 100ml	Surge Laboratories Private Limited.	Bacip IV Infusion	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
753	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Surge Laboratories Private Limited.	Lisodim Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
754	124	Gentamycin Injection 80mg	Surge Laboratories Private Limited.	Genxat Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
755	146	Ipratropium Bromide Nebulizing Solution	Surge Laboratories Private Limited.	Ventpro Nebuliser Solution	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
756	148	Iron Sucrose Injection 100mg/5ml	Surge Laboratories Private Limited.	Megafer Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
757	156	Lignocaine (hydrochloride) 2% Injection	Surge Laboratories Private Limited.	Lidoject Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
758	177	Metronidazole 500mg/100ml infusion	Surge Laboratories Private Limited.	Intobix IV Infusion	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
759	193	Normal Saline Infusion 0.9% 100ml	Surge Laboratories Private Limited.	Celine Infusion	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
760	206	Paracetamol 1 gm/ 100ml Infusion	Surge Laboratories Private Limited.	Feveral IV Infusion	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
761	259	Suxamethonium (chloride) Injection 100 mg/2ml	Surge Laboratories Private Limited.	Neuronium	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
762	269	Tramadol HCl Injection 100mg/2ml	Surge Laboratories Private Limited.	Trompol Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
763	271	Tranexamic Acid Injection 500mg/5ml	Surge Laboratories Private Limited.	Tranmax Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
764	279	Vitamin D3 Injection 5mg	Surge Laboratories Private Limited.	Trick-D	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
765	281	Water for injection 10 ml Sterile	Surge Laboratories Private Limited.	Water For Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>
766	282	Water for injection 5 ml Sterile	Surge Laboratories Private Limited.	Water For Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: Undertakings not notarized. Clause no. 15: Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan not attached. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.</p> <p><u>Itemwise</u> Clause no. 4, 6, 7, 8, 9, 10 & 11: undertakings not notarized. Clause no. 8: Daily production capacity of quoted item not attached.</p>		<p>Firmwise Clause no. 2, 7, 8, 9, 10, 11, 12, 13, 16, 20 & 21: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 15: The firm did not provide Building fitness certificate of its manufacturing site issued by concerned authority or Layout plan; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 17: Injection CLOTIDE declared spurious vide TRA No. 01-139001386 dated: 08-08-2019.; hence, grievance of the firm was not accepted to the extent of this parameter.</p> <p>Itemwise Clause no. 4, 6, 7, 8, 9, 10 & 11: The firm provided requisite undertakings on notarized stamp paper, which were accepted. Clause no. 8: The firm provided Daily production capacity of quoted item, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
767	51	Calcium Carbonate Tablets (equivalent to 400-500mg elemental calcium)	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	DECALC PLUS	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification	The technical evaluation report has been uploaded on the website of Health Department, Punjab. As per PPRA rules, it is requested you, kindly allow us to appear in front of honorable grievance committee. Sir, the marks of our few attached documents are missing / over looked. We are sending the copies again please re-consider the marks. Attached with this application are the following documents 1. Undertaking – Calibrated and Validated Stability Chambers 2. Calibration and Validation Certificates of Stability Chambers 3. Drug Registration Letter – DECALC PLUS Tablets (500 mg Elemental Calcium) 4. Drug Registration letter – HEMESOL Inj (20 mg / ml) 5. Drug Registration letter – MOXICIN Eye Drops (5 mg / ml) 6. Drug Registration letter – TIMOSOL Eye Drops (5 mg/ ml) We are looking forward for your kind consideration.	Mst. Asifa Nazir, Product Manager from M/s The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: Firmwise Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted. Itemwise Clause no. 2: Quoted specification does not comply with advertised specification
768	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	CINOX	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		Firmwise Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
769	118	Escitalopram Tablets 10mg	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	ESLOPRA M	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		Firmwise Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
770	119	Ferrous salt + Folic Acid Capsule/Tablets	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	HEMIFERE	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		Firmwise Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
771	147	Iron iii Hydroxide Polymaltose Syrup	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	HEMIFERE	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
772	148	Iron Sucrose Injection 100mg/5ml	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	HEMESOL	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 20mg/5ml is not as per the advertised strength of PQ document as well as not as per the strength mentioned in the DRC of quoted item i.e., 20mg/ml.		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 20mg/5ml is not as per the advertised strength of PQ document as well as not as per the strength mentioned in the DRC of quoted item i.e., 20mg/ml.
773	152	Lactulose Syrup 3.335gm/5ml to 3.35gm/5ml	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	BILAGOL-L	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
774	154	Levofloxacin Tablet 250mg	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	LEQUIX	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
775	181	Midazolam Injection 1mg/ml	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	SEDAZOL AM	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
776	186	Moxifloxacin Eye drops 0.5%(5ml)	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	MOXICIN	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 5mg/5ml is not as per the strength mentioned in the DRC of quoted item i.e., 5mg/ml.		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 5mg/5ml is not as per the strength mentioned in the DRC of quoted item i.e., 5mg/ml.
777	188	Nalbuphine Hcl Injection 10mg/ml	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	NIXA	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
778	190	Naproxen Sodium Tablet 550 mg (equivalent to 500mg Naproxen)	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	APROXEN DS	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
779	266	Timolol (hydrogen maleate) Eye Drops 0.5%	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	TIMOSOL	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 5mg/5ml is not as per the strength mentioned in the DRC of quoted item i.e., 5mg/ml.		<u>Firmwise</u> Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted. <u>Itemwise</u> Clause no. 2: The quoted strength of quoted item i.e., 5mg/5ml is not as per the strength mentioned in the DRC of quoted item i.e., 5mg/ml.
780	267	Tobramycin + Dexamethasone Eye Drops	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	TOBRA - D	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
781	279	Vitamin D3 Injection 5mg	The Schazoo Pharmaceutical Laboraotries (Pvt) Ltd	ORAL D 3	Not Qualified	<u>Firmwise</u> Clause no. 12: Calibration certificates of stability chambers not attached.		<u>Firmwise</u> Clause no. 3: The firm did not provided valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP; hence, grievance of the firm was not accepted to the extent of this parameter. Clause no. 12: The firm provided calibration certificate of stability chambers, which were accepted.
782	17	Ammonium Chloride+ Aminophylline+ other ingredients as expectorant Syrup/Susp.	THE SEARLE COMPANY LIMITED	HYDRYLLI N	Not Qualified	<u>Itemwise</u> Clause no. 2: The quoted pack size of quoted item is not mentioned in DRC.	Our humble submissions are as under: Inq. No. 17 - Ammonium Chloride + Aminophylline + other ingredients as expectorant Syrup / Susp. (Hydryllin Syrup 120ml): As per Clause No.2: The Drug Registration Certificate of quoted pack size i.e. 120ml of said item is attached. Inq. No. 77 - Ciprofloxacin (Hydrochloride) Tablets 500mg (Cinoxin Tablet 500mg): As per Clause No.2: The Toll Manufacturing Contract between M/s. The Searle Company Limited and M/s. Searle IV Solutions (Pvt) Ltd. is attached.	Mr. Mehraaz, Senior Institutional Sales from M/s The Searle Compnay Limited attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 120ml Pack, which was accepted.
783	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	THE SEARLE COMPANY LIMITED	CINOXIN	Not Qualified	<u>Itemwise</u> Clause no. 2: DRC of the quoted item is on the name of M/s Searl IV Solutions. Moreover, toll manufacturing approval from DRAP not attached.	Inq. No. 94 - Dextromethorphan + Diphenhydramine / CPM / Pseudoephedrine + others ingredients as antitussive / dry cough Syrup / Susp. (Hydryllin-DM Syrup 120ml): As per Clause No.2: The Drug Regulatory of Pakistan's approval of quoted pack size i.e. 120ml of said item is attached.	<u>Itemwise</u> Clause no. 2: DRC of the quoted item is on the name of M/s Searl IV Solutions. Moreover, toll manufacturing approval from DRAP; hence, grievance of the firm was not accepted to the extent of this parameter.
784	94	Dextromethorphan + Diphenhydramine/C PM/Pseudoephedrine+ others ingredients as antitussive/dry cough Syrup/Susp.	THE SEARLE COMPANY LIMITED	HYDRYLLI N-DM	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP approval for the quoted pack size not attached.	Inq. No. 127 - Glyceryl Trinitrate (S.R) Tablet 2.6mg (Sustac Tablet 2.6mg): As per Clause No.2: The Drug Regulatory of Pakistan's approval of quoted pack size i.e. 30's of said item is attached.	<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 120ml Pack, which was accepted.
785	127	Glyceryl Trinitrate (S.R) Tablet 2.6mg	THE SEARLE COMPANY LIMITED	SUSTAC	Not Qualified	<u>Itemwise</u> Clause no. 2: The quoted pack size of quoted item is not mentioned in DRC.	Inq. No. 128 - Glyceryl Trinitrate (S.R) Tablet 6.4mg (Sustac Tablet 6.4mg): As per Clause No.2: The Drug Regulatory of Pakistan's approval of quoted pack size i.e. 30's of said item is attached.	<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 30's Pack, which was accepted.
786	128	Glyceryl Trinitrate (S.R) Tablet 6.4mg	THE SEARLE COMPANY LIMITED	SUSTAC 6.4MG	Not Qualified	<u>Itemwise</u> Clause no. 2: The quoted pack size of quoted item is not mentioned in DRC.	Inq. No. 176 - Metronidazole (Benzonate) Syrup 200mg/5ml (Metrozine Susp. 200mg):	<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 30's Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
787	176	Metronidazole (Benzoate) Syrup 200 mg / 5ml	THE SEARLE COMPANY LIMITED	METROZIN E	Not Qualified	<u>Itemwise</u> Clause no. 1: Quoted item section not enlisted on GMP certificate. Clause no. 2: Approval for the quoted pack size not attached.	<p>200mg/5ml (Metrozine Susp. 200mg): As per Clause No.1: The GMP Certificate (enlisted with section of quoted item) is attached. As per Clause No.2: The Drug Regulatory of Pakistan's approval of quoted pack size i.e. 90ml of said item is attached.</p> <p>Inq. No.177-Metronidazole (Benzonate) 500mg/100ml Infusion (Metrozine RFU Inj. 500mg): As per Clause No. 2: The Drug Registration Certificate's transfer letter of the said item from M/s. Searle Pakistan Limited to M/s. The Searle Company Limited is attached.</p> <p>Inq. No. 202 - ORS Sachet (WHO Formulatoin) (Peditral Low Sachet 22G): As per Clause No.2: The Drug Regulatory of Pakistan's approval of quoted pack size i.e. 20's of said item is attached. It is further submitted that during On-line submission due to typographical mistake</p>	<p><u>Itemwise</u> Clause no. 1: The provided valid GMP certificate, which was accepted. Clause no. 2: The firm provided DRAP approval of 90ml Pack, which was accepted.</p>
788	177	Metronidazole 500mg/100ml infusion	THE SEARLE COMPANY LIMITED	METROZIN E RFU INJECTION	Not Qualified	<u>Itemwise</u> Clause no. 2: DRC of quoted item is on the name of M/s Searle Pakistan Limited.		<p><u>Itemwise</u> Clause no. 2: DRC of quoted item is on the name of M/s Searle Pakistan Limited; hence, grievance of the firm was not accepted to the extent of this parameter.</p>
789	202	ORS Sachet (WHO Formulation)	THE SEARLE COMPANY LIMITED	PEDITRAL LOW	Not Qualified	<u>Itemwise</u> Clause no. 2: Approval for the quoted pack size by DRAP not attached.		<p><u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 20's Pack, which was accepted.</p>
790	206	Paracetamol 1 gm/ 100ml Infusion	THE SEARLE COMPANY LIMITED	NUBEROL P INJECTIONS	Not Qualified	<u>Itemwise</u> Clause no. 2: Approval for contract manufacturing of quoted item by DRAP not attached. Clause no. 3: Experience of quoted item from date of registration is less than one year.		<p>The firm did not contest for the quoted item.</p>
791	284	Zinc Sulphate Syrup 20mg/5ml.	THE SEARLE COMPANY LIMITED	DIAZINC	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)	<p>The firm did not contest for the quoted item.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
792	80	Ciprofloxacin Injection 200mg / 100ml	Unisa pharmaceutical industries LTD	UNICIPRO X	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>	<p>This is with reference to subject cited above, our firm participated in prequalification DGHS Punjab, Primary & Secondary Healthcare Department products Sr# 577,1578,1579,1580,1581,1582,1583,1584,1585,1586,1587,1588,1589 & Inq # 80,95,96,98,162,177,192,193,210,239,240,281 & 282 for the year 2022-2023, where the above mentioned Sr # and Inq# has been declared not qualified.</p> <p>Firmwise Explanation: Clause No.14: FBR Income Tax Return / Sale Tax Return for the year 2018-19,2019-20,2020-2021 and Bank Statements are attached, therefore please accept our grievance and declare status qualified. Clause No.17: Undertaking regarding Spurious & Adulterated is attached, therefore please accept our grievance and declare status qualified. Itemwise Explanation: Clause No.7 & 8: Daily Production capacity and maximum batch size of quoted item on notarized stamp paper is attached, therefore please accept our grievance and declare status qualified.</p>	<p>Mr. Muhammad Usman Hameed, Distributor of M/s Unisa pharmaceutical industries Ltd attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report.</p> <p>The committee after due deliberation and discussion decided that:</p> <p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
793	95	Dextrose 10% 1000ml	Unisa pharmaceutical industries LTD	UNISOL-10	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>	<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>	

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
794	96	Dextrose Infusion 5%, 1000ml)	Unisa pharmaceutical industries LTD	UNISOL-5	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
795	98	Dextrose+Saline (1000ml) Infusion 5%w/v +0.9%w/v	Unisa pharmaceutical industries LTD	UNISOL-DS	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
796	162	Mannitol (500ml) Infusion 20% w/v	Unisa pharmaceutical industries LTD	UNIRETIC-20	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
797	177	Metronidazole 500mg/100ml infusion	Unisa pharmaceutical industries LTD	Unizol	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached. <u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted. <u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.
798	192	Normal Saline Infusion 0.9% (1000ml)	Unisa pharmaceutical industries LTD	Unisol NS	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached. <u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted. <u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.
799	193	Normal Saline Infusion 0.9% 100ml	Unisa pharmaceutical industries LTD	Unisol-NS	Not Qualified	<u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached. <u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.		<u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted. <u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
800	210	Peeds Soln Infusion 1/5 Normal Saline infusion (Paeds solution) 500 ml	Unisa pharmaceutical industries LTD	Unisol Peeds	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
801	239	Ringer's Lactate (1000ml) Infusion	Unisa pharmaceutical industries LTD	Unisol-RL	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
802	240	Ringer's Lactate (500ml)	Unisa pharmaceutical industries LTD	Unisol RL	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
803	281	Water for injection 10 ml Sterile	Unisa pharmaceutical industries LTD	Unisolvent	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
804	282	Water for injection 5 ml Sterile	Unisa pharmaceutical industries LTD	UNISOLVE NT	Not Qualified	<p><u>Firmwise</u> Clause no. 14: FBR income/sales tax returns and bank statement for FY 2020-21 not attached. Clause no. 17: Undertaking regarding Spurious & Adulterated not attached.</p> <p><u>Itemwise</u> Clause no. 7 & 8: Daily production capacity and maximum batch size of quoted item on notarized stamp paper not attached.</p>		<p><u>Firmwise</u> Clause no. 14: The firm provided FBR income/sales tax returns and bank statement for FY 2020-21, which was accepted. Clause no. 17: The firm provided undertaking regarding Spurious & Adulterated, which was accepted.</p> <p><u>Itemwise</u> Clause no. 7 & 8: The firm provided Daily production capacity and maximum batch size of quoted item on notarized stamp paper, which was accepted.</p>
805	3	Acyclovir Injection 250 mg	Wilshire Labs (Pvt) Ltd.	Virq Injection	Not Qualified	<p><u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.</p>	<p>The Director General Health Services 24 Cooper Road, Lahore 2. Chairman Grievance Redressal Committee. Subject: Grievance Complaint under Rule 67 of the Punjab Procurement Rules, 2014, against Technical Evaluation Report regarding Prequalification of Drugs Medicine Phase 1 for Financial Year 2022-2023. Dear Sir, 1. With reference to the subject, we participated in the Prequalification of Drugs Medicines Phase 1 for the financial year 2022-23 and your technical committee rejected our firm all quoted items on the base of (Firm wise Clause no. 17: The statement of undertaking is not as prescribed in the PQ document) 2. In continuation of above statement, it is worthwhile to mention here that we Wilshire Labs has submitted Undertaking as per clause # 17 of PQ Documents & we once again submitting the same as well as we have also marked "YES" this clause in knockdown Criteria at PQOD.</p>	<p>Mr. Shahbaz Akhtar, Assistant Manager Institutional Sales from M/s Wilshire Labs (Pvt) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Application Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.</p>
806	16	Amlodipine Tablets 5 mg	Wilshire Labs (Pvt) Ltd.	Caprinza Tablet	Not Qualified	<p><u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.</p>		<p><u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.</p>

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
807	37	Atenolol Tablet 50mg	Wilshire Labs (Pvt) Ltd.	Zamcil Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.	PRAYER In light of the foregoing, you are most and humbly requested to accept the instant Grievance Complaint in the terms provided hereinabove and declare Wilshire Labs all quoted products to be Technically Prequalified, so that we can also get the chance to serve a well-known institute with the best quality of medicine.	<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
808	38	Atorvastatin Tablets 20mg	Wilshire Labs (Pvt) Ltd.	Lastolip Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
809	41	Azithromycin Capsules/Tab 250mg	Wilshire Labs (Pvt) Ltd.	Zeecin Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
810	42	Azithromycin Capsules/Tab 500mg	Wilshire Labs (Pvt) Ltd.	Zeecin Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
811	43	Azithromycin Susp 200mg/5ml	Wilshire Labs (Pvt) Ltd.	Zeecin Suspension	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
812	57	Cefixime Capsule/Tablets 400mg	Wilshire Labs (Pvt) Ltd.	Secure Capsule	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
813	58	Cefixime Suspension 100mg/5ml	Wilshire Labs (Pvt) Ltd.	Secure Suspension	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
814	59	Cefixime Suspension 200mg/5ml	Wilshire Labs (Pvt) Ltd.	Secure DS Suspension	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
815	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Wilshire Labs (Pvt) Ltd.	Triax Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
816	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Wilshire Labs (Pvt) Ltd.	Triax Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
817	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Wilshire Labs (Pvt) Ltd.	Triax Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
818	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Wilshire Labs (Pvt) Ltd.	Quash Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
819	80	Ciprofloxacin Injection 200mg / 100ml	Wilshire Labs (Pvt) Ltd.	Quash Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
820	81	Clarithromycin Suspension 125mg/5ml	Wilshire Labs (Pvt) Ltd.	Ranker Suspension	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
821	82	Clarithromycin Tablets 500mg	Wilshire Labs (Pvt) Ltd.	Ranker Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
822	85	Clopidogrel Tablets 75 mg	Wilshire Labs (Pvt) Ltd.	Flexiflow Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
823	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Wilshire Labs (Pvt) Ltd.	Zwitter Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
824	118	Escitalopram Tablets 10mg	Wilshire Labs (Pvt) Ltd.	Cheer Up Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
825	120	Fluconazole Capsules 150mg	Wilshire Labs (Pvt) Ltd.	Alfumet Capsule	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
826	126	Glimepiride Tablets 2mg	Wilshire Labs (Pvt) Ltd.	Glyset Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
827	148	Iron Sucrose Injection 100mg/5ml	Wilshire Labs (Pvt) Ltd.	Fiore Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
828	154	Levofloxacin Tablet 250mg	Wilshire Labs (Pvt) Ltd.	Neumo Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
829	185	Montelukast Tablets 10 mg	Wilshire Labs (Pvt) Ltd.	Tair Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
830	199	Omeprazole Capsule 20mg	Wilshire Labs (Pvt) Ltd.	Benzim Capsule	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
831	200	Omeprazole Injection 40mg	Wilshire Labs (Pvt) Ltd.	Benzim Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
832	201	Ondansetron injection 4mg/2ml	Wilshire Labs (Pvt) Ltd.	Onwil Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
833	203	Oseltamivir 75mg Capsule/Tablet	Wilshire Labs (Pvt) Ltd.	Pronto Capsule	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
834	209	Paracetamol Tablet 500 mg	Wilshire Labs (Pvt) Ltd.	Paracetamol Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
835	268	Tramadol HCl Capsule/Tablet 50 mg	Wilshire Labs (Pvt) Ltd.	Zultra Tablet	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
836	269	Tramadol HCl Injection 100mg/2ml	Wilshire Labs (Pvt) Ltd.	Zultra Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
837	271	Tranexamic Acid Injection 500mg/5ml	Wilshire Labs (Pvt) Ltd.	Xavene Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
838	276	Vancomycin (HCl) Injection 500 mg	Wilshire Labs (Pvt) Ltd.	Zalpax Injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
839	281	Water for injection 10 ml Sterile	Wilshire Labs (Pvt) Ltd.	Water for injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
840	282	Water for injection 5 ml Sterile	Wilshire Labs (Pvt) Ltd.	Water for injection	Not Qualified	<u>Firmwise</u> Clause no. 17: The statement of undertaking is not as per described in the PQ document.		<u>Firmwise</u> Clause no. 17: The firm provided requisite undertaking as prescribed in the PQ document, which was accepted.
841	41	Azithromycin Capsules/Tab 250mg	Wimits Pharmaceuticals (Pvt.) Ltd	Azotrax 250mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.	With reference to your query stated in clause 17 regarding report on our product wimlox having batch no WX008 by DTL Faisalabad via report TRA no 01-56005355 dated 24/07/2020, we want to bring into your kind notice that PQCB has been issued us warning letter against this batch number. (Copy attached) After the first report of Wx008 from DTL Faisalabad, CDC office recollected the samples from the same supply of same batch of Wimlox Batch#Wx008 and send to DTL Lahore, reported via TRA 01-143005559 dated 14/09/2020 & TRA 01-143005555 dated 14/09/2020. For your kind information the PQCB has issued warning against this batch#Wx008. Regarding your query stated in clause 17 regarding TRA#01-149001502 dated 17/09/2020 having Batch# WX007 Wimlox Tab, was collected by area Drug Inspector Allama Iqbal town Lahore from our premises / plant which was not a public sector supplies as it does not fall in your criteria mentioned in clause 17 (see attached copy) According to above facts you are requested please accept our grievance and prequalify our Company so that we can participate in healthy competition for procurement of medicine in the province of Punjab.	Mr. Abdul Jabbar, Executive Director from M/s attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
842	42	Azithromycin Capsules/Tab 500mg	Wimits Pharmaceuticals (Pvt.) Ltd	Azotrax 500mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
843	67	Cetirizine Syrup/liquid/solution 5mg / 5ml.	Wimits Pharmaceuticals (Pvt.) Ltd	Cetrido 5mg/5ml Syrup	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
844	68	Cetirizine Tablets 10mg	Wimits Pharmaceuticals (Pvt.) Ltd	Cetrido 10mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
845	77	Ciprofloxacin (Hydrochloride) Tablets 500 mg	Wimits Pharmaceuticals (Pvt.) Ltd	Solo-cip 500mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
846	85	Clopidogrel Tablets 75 mg	Wimits Pharmaceuticals (Pvt.) Ltd	Wascorel 75mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
847	100	Diclofenac (Sodium) Capsule/Tablets 50 mg	Wimits Pharmaceuticals (Pvt.) Ltd	Painsa 50mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
848	101	Diclofenac (Sodium) Injection 75mg in 3 ml Ampoule	Wimits Pharmaceutical s (Pvt.) Ltd	Painsa 75mg/3ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
849	104	Dimenhydrinate 50mg/ml injection	Wimits Pharmaceutical s (Pvt.) Ltd	Mavinat 50mg/ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
850	107	Domperidone 10mg Tablet	Wimits Pharmaceutical s (Pvt.) Ltd	Donits 10mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
851	108	Dopamine (hydrochloride) Injection 200mg/5ml	Wimits Pharmaceutical s (Pvt.) Ltd	Dopa 200mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
852	109	Doxycycline (hyclate) Capsules 100mg	Wimits Pharmaceutical s (Pvt.) Ltd	Microdox 100mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
853	110	Drotaverine 40mg/2ml Injection	Wimits Pharmaceutical s (Pvt.) Ltd	Drotamit 40mg/2ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
854	111	Drotaverine Tablet 40mg	Wimits Pharmaceutical s (Pvt.) Ltd	Drotamit 40mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
855	118	Escitalopram Tablets 10mg	Wimits Pharmaceutical s (Pvt.) Ltd	Esitor 10mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
856	120	Fluconazole Capsules 150mg	Wimits Pharmaceutical s (Pvt.) Ltd	Funol 150mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
857	122	Furosemide Injection 20mg/2ml	Wimits Pharmaceutical s (Pvt.) Ltd	Dreetay 20mg/2ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
858	138	Ibuprofen Susp. 100mg/5ml	Wimits Pharmaceutical s (Pvt.) Ltd	Ibuprofen 100mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
859	147	Iron iii Hydroxide Polymaltose Syrup	Wimits Pharmaceutical s (Pvt.) Ltd	P-malt 50mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
860	154	Levofloxacin Tablet 250mg	Wimits Pharmaceutical s (Pvt.) Ltd	Levodor 250mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
861	176	Metronidazole (Benzoate) Syrup 200 mg / 5ml	Wimits Pharmaceutical s (Pvt.) Ltd	Metogyl 200mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
862	185	Montelukast Tablets 10 mg	Wimits Pharmaceutical s (Pvt.) Ltd	Askat 10mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
863	188	Nalbuphine Hcl Injection 10mg/ml	Wimits Pharmaceuticals (Pvt.) Ltd	Nal-bee 10mg/ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
864	198	Ofloxacin 200mg Tablets	Wimits Pharmaceuticals (Pvt.) Ltd	Ofax 200mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
865	199	Omeprazole Capsule 20mg	Wimits Pharmaceuticals (Pvt.) Ltd	Oray 20mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
866	245	Salbutamol Syrup	Wimits Pharmaceuticals (Pvt.) Ltd	Ventosal 2mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
867	268	Tramadol HCl Capsule/Tablet 50 mg	Wimits Pharmaceuticals (Pvt.) Ltd	W-dol 50mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
868	269	Tramadol HCl Injection 100mg/2ml	Wimits Pharmaceuticals (Pvt.) Ltd	W-dol 100mg/2ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020. <u>Itemwise</u> Clause no. 2: DRC renewal not attached		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
869	271	Tranexamic Acid Injection 500mg/5ml	Wimits Pharmaceuticals (Pvt.) Ltd	Tranza 500mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
870	275	Valproic acid (as sodium) Tablets 500mg	Wimits Pharmaceuticals (Pvt.) Ltd	Dpiro 500mg	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
871	279	Vitamin D3 Injection 5mg	Wimits Pharmaceuticals (Pvt.) Ltd	Cal-dee 5mg/ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020. <u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
872	284	Zinc Sulphate Syrup 20mg/5ml.	Wimits Pharmaceuticals (Pvt.) Ltd	Zincwim 20mg/5ml	Not Qualified	<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020.		<u>Firmwise</u> Clause no. 17: Tablet Wimlox declared adulterated vide TRA No. 01-56005355 dated: 24-07-2020; TRA No. 01-149001502 dated: 17-09-2020; TRA No. 01-143005559 dated: 14-09-2020; TRA No. 01-143005555 dated: 14-09-2020; hence, grievance of the firm was not accepted to the extent of this parameter.
873	18	Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets	Zafa Pharmaceutical Laboratories (Private) Limited	Zamoclav	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	We would like to inform you that we applied our 77 items (Drugs/Medicines) for pre-qualification with the Director General Health Services, Punjab, Lahore / Secretary, Government of the Punjab, Primary & Secondary Healthcare Department, Lahore by providing / enclosing therewith all the pre-requisites for the purpose. It has been noted through the Technical Evaluation Report uploaded by the Director General Health Services, Punjab, Lahore / Secretary, Government of the Punjab, Primary & Secondary Healthcare Department, Lahore that our 33 items have not been qualified on the basis of (1) Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached, (2) Quoted specification does not comply with advertised specification, (3) Samples Substandard of quoted item (over 5%) from (01-01-2021) and (4) DRAP approval of quoted pack not attached. We are pleased to enclose along with following documentation for revisit of our offers for qualification of offered items:- Inq No Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of Non-qualifying Completion of short-falls ZAFSA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED, B-10, NORTH KARACHI, KARACHI 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets Zamoclav Tablet 1gm 6 Firmwise Clause No.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 19 Amoxicillin (trihydrate) Capsules/tablets 250mg Zoxicillin Capsule 250mg 19 20 Amoxicillin	Mr. Qamar Bhatti, Distributor of M/s attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Knock Down Criteria and announced PQ Technical Evaluation Report. The committee after due deliberation and discussion decided that: <u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
874	19	Amoxicillin (trihydrate) Capsules/tablets 250mg	Zafa Pharmaceutical Laboratories (Private) Limited	Zoxicillin	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached, (2) Quoted specification does not comply with advertised specification, (3) Samples Substandard of quoted item (over 5%) from (01-01-2021) and (4) DRAP approval of quoted pack not attached. We are pleased to enclose along with following documentation for revisit of our offers for qualification of offered items:- Inq No Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of Non-qualifying Completion of short-falls ZAFSA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED, B-10, NORTH KARACHI, KARACHI 18 Amoxicillin (as trihydrate) 875mg + Clavulanic Acid (as Potassium) 125mg Tablets Zamoclav Tablet 1gm 6 Firmwise Clause No.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 19 Amoxicillin (trihydrate) Capsules/tablets 250mg Zoxicillin Capsule 250mg 19 20 Amoxicillin	<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
875	20	Amoxicillin (trihydrate) Capsules/tablets 500 mg	Zafa Pharmaceutical Laboratories (Private) Limited	Zoxicillin	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 19 Amoxicillin (trihydrate) Capsules/tablets 250mg Zoxicillin Capsule 250mg 19 20 Amoxicillin	<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
876	21	Amoxicillin (trihydrate) Dispersible tablets 500mg	Zafa Pharmaceutical Laboratories (Private) Limited	Dispermox	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 19 Amoxicillin (trihydrate) Capsules/tablets 250mg Zoxicillin Capsule 250mg 19 20 Amoxicillin	<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
884	29	Ampicillin Glass Vial, Injection 250 mg (as sodium salt)	Zafa Pharmaceutical Laboratories (Private) Limited	Zampicillin	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	authority or layout plan not attached. Approved copy of requisite layout plan is attached. 63 Cefurexime (Sodium) Injection 750mg Zafurox Injection 750mg Vial 64 Cephadrine Capsule 500mg Cephgen-1 Capsule 500mg 12 65 Cephadrine Injection 500mg Cephgen-1 Injection 500mg Vial 66 Cephadrine Susp 125mg/5ml Cephgen-1 Dry Powder Susp. 125mg/5ml 30ml 261 Tazobactam+Piperacillin Injection 500mg+4gm Piperataz Injection 4.5gm Vial Inq No Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of Non-qualifying Completion of short-falls ZAFSA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED, B-22, F.B. AREA, KARACHI 281 Water for injection 10 ml Sterile Water For Injection 10ml Ampoule Itemwise: Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 10ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached). We will supply the item Free of Cost as Solvent with Dry Powder for Injection 282 Water for injection 5 ml Sterile Water For injection 5ml Ampoule Itemwise Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 5ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached).	Firmwise Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
885	39	Atracurium (besylate) Injection 10mg/ml	Zafa Pharmaceutical Laboratories (Private) Limited	Relaxtron	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification	30ml 261 Tazobactam+Piperacillin Injection 500mg+4gm Piperataz Injection 4.5gm Vial Inq No Generic Name Quoted Brand, Dosage Form and Strength Pack Size Reason of Non-qualifying Completion of short-falls ZAFSA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED, B-22, F.B. AREA, KARACHI 281 Water for injection 10 ml Sterile Water For Injection 10ml Ampoule Itemwise: Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 10ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached). We will supply the item Free of Cost as Solvent with Dry Powder for Injection 282 Water for injection 5 ml Sterile Water For injection 5ml Ampoule Itemwise Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 5ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached).	<u>Itemwise</u> Clause no. 2: The firm provided DRC, which was accepted.
886	47	Betamethasone Cream 0.1%	Zafa Pharmaceutical Laboratories (Private) Limited	Betadip	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification	Water For Injection 10ml Ampoule Itemwise: Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 10ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached). We will supply the item Free of Cost as Solvent with Dry Powder for Injection 282 Water for injection 5 ml Sterile Water For injection 5ml Ampoule Itemwise Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 5ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached).	The firm did not contest for the quoted item.
887	57	Cefixime Capsule/Tablets 400mg	Zafa Pharmaceutical Laboratories (Private) Limited	Ceforal-3	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	Water For Injection 10ml Ampoule Itemwise: Clause No. 2: DRAP approval of quoted pack not attached. Approved pack size of the item is Ampoule of 5ml but by mistake, the pack size was mentioned as 96 Ampoules (registration of 1's pack is attached).	Firmwise Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
888	58	Cefixime Suspension 100mg/5ml	Zafa Pharmaceutical Laboratories (Private) Limited	Ceforal-3	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	We will supply the item Free of Cost as Solvent with Dry Powder for Injection 283 Zinc Sulphate Dispersible Tablet 20 mg Zindigi Tablet 20mg 14 Itemwise: Clause No. 2: DRAP approval of quoted pack not attached. Registration is attached with pack size. (Typo Mistake) our pack size is 20's ZAFSA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED. A-46, NORTH KARACHI 89 Combined Oral Contraceptive Pill (21 Tabs norgestril and ethinyl estradiol and 7 Tabs ferrous fumarate tablets Famila 28F Tablet 0.15+0.03+0.75 28 Firmwise Clause No.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 166 Medroxyprogesterone acetate Inj. 150mg/ml Famila Injection 150mg 1ml Vial 182 Misoprostol Tablets 200mcg S.T. Mom Tablet 200mcg 10 Since we have completed all the short-falls, hence,	Firmwise Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
889	60	Ceftriaxone (Sodium) Injection 1gm (I.V)	Zafa Pharmaceutical Laboratories (Private) Limited	Zeftrox IV	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED. A-46, NORTH KARACHI 89 Combined Oral Contraceptive Pill (21 Tabs norgestril and ethinyl estradiol and 7 Tabs ferrous fumarate tablets Famila 28F Tablet 0.15+0.03+0.75 28 Firmwise Clause No.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 166 Medroxyprogesterone acetate Inj. 150mg/ml Famila Injection 150mg 1ml Vial 182 Misoprostol Tablets 200mcg S.T. Mom Tablet 200mcg 10 Since we have completed all the short-falls, hence,	Firmwise Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
890	61	Ceftriaxone (Sodium) Injection 250mg (I.V)	Zafa Pharmaceutical Laboratories (Private) Limited	Zeftrox IV	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED. A-46, NORTH KARACHI 89 Combined Oral Contraceptive Pill (21 Tabs norgestril and ethinyl estradiol and 7 Tabs ferrous fumarate tablets Famila 28F Tablet 0.15+0.03+0.75 28 Firmwise Clause No.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached. Approved copy of requisite layout plan is attached. 166 Medroxyprogesterone acetate Inj. 150mg/ml Famila Injection 150mg 1ml Vial 182 Misoprostol Tablets 200mcg S.T. Mom Tablet 200mcg 10 Since we have completed all the short-falls, hence,	Firmwise Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
891	62	Ceftriaxone (Sodium) Injection 500 mg (I.V)	Zafa Pharmaceutical Laboratories (Private) Limited	Zeftrox IV	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.	it is requested to please prequalify our offered items (Drugs/ Medicines) for healthy competition.	<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
892	63	Cefurexime (Sodium) Injection 750mg	Zafa Pharmaceutical Laboratories (Private) Limited	Zafurox	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
893	64	Cephradine Capsule 500mg	Zafa Pharmaceutical Laboratories (Private) Limited	Cephgen-1	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
894	65	Cephradine Injection 500mg	Zafa Pharmaceutical Laboratories (Private) Limited	Cephgen-1	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
895	66	Cephradine Susp 125mg/5ml	Zafa Pharmaceutical Laboratories (Private) Limited	Cephgen-1	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
896	89	Combined Oral Contraceptive Pill (21 Tabs norgestrel and ethinyl estradiol and 7 Tabs ferrous fumarate tablets)	Zafa Pharmaceutical Laboratories (Private) Limited	Famila 28F	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance for the Firm	Decision by the Committee
897	166	Medroxyprogesterone acetate Inj. 150mg/ml	Zafa Pharmaceutical Laboratories (Private) Limited	Famila	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
898	182	Misoprostol Tablets 200mcg	Zafa Pharmaceutical Laboratories (Private) Limited	S.T. Mom	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
899	190	Naproxen Sodium Tablet 550 mg (equivalent to 500mg Naproxen)	Zafa Pharmaceutical Laboratories (Private) Limited	Naptrol	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification		The firm did not contest for the quoted item.
900	191	Nifedipine 10mg Capsule/tablet	Zafa Pharmaceutical Laboratories (Private) Limited	Nifedil	Not Qualified	<u>Itemwise</u> Clause no. 6: Samples Substandard of quoted item (over 5%) from (01-01-2021)		The firm did not contest for the quoted item.
901	259	Suxamethonium (chloride) Injection 100 mg/2ml	Zafa Pharmaceutical Laboratories (Private) Limited	Zuselax	Not Qualified	<u>Itemwise</u> Clause no. 2: Quoted specification does not comply with advertised specification		The firm did not contest for the quoted item.
902	261	Tazobactam+Piperacillin Injection 500mg+4gm	Zafa Pharmaceutical Laboratories (Private) Limited	Piperataz	Not Qualified	<u>Firmwise</u> Clause no.15: Building fitness certificate of manufacturing site issued by concerned authority or layout plan not attached.		<u>Firmwise</u> Clause no.15: The firm provided Building fitness certificate of manufacturing site issued by concerned authority and layout plan, which was accepted.
903	281	Water for injection 10 ml Sterile	Zafa Pharmaceutical Laboratories (Private) Limited	Water For Injection	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP approval of quoted pack not attached.		<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 1's Pack, which was accepted.

Sr.	Inq No	Generic Name	Company Name	Quoted Brand	Status	Remarks	Grievance fo the Firm	Decision by the Committee
904	282	Water for injection 5 ml Sterile	Zafa Pharmaceutical Laboratories (Private) Limited	Water For injection	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP approval of quoted pack not attached.		<u>Itemwise</u> Clause no. 2: The firm provided DRAP approval of 1's Pack, which was accepted.
905	283	Zinc Sulphate Dispersible Tablet 20 mg	Zafa Pharmaceutical Laboratories (Private) Limited	Zindigi	Not Qualified	<u>Itemwise</u> Clause no. 2: DRAP approval of quoted pack not attached.		<u>Itemwise</u> Clause no. 2: The firm did not provide DRAP approval of quoted pack; hence, grievance of the firm was not accepted to the extent of this parameter.