MINUTES OF 296th MEETING OF REGISTRATION BOARD HELD ON 8th, 9th & 10th SEPTEMBER 2020.

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Drug Regulatory Authority of Pakistan
T.F. Complex, Mauve Area, G-9/4
Islamabad.

296th meeting of Registration Board was held on 08th- 10th September, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr. Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP. The meeting started with recitation of the Holy Verses.

The meeting was attended by the following:-

1.	Dr. Rafeeq Alam Khan, Meritorious Professor, Faculty of Pharmacy, Ziauddin University, Karachi.	Member
2.	Lt.Gen.(R) Prof.Dr. Karamat Ahmed Karamat (HI-M, SI-M) Former Surgeon General Pakistan	Member
3.	Maj.Gen. (R) Dr.Tahir Mukhtar Sayed, Inspector General (Hospitals), Fauji Foundation, Rawalpindi	Member
4.	Mr. Iftikhar A.Choudhary, Hospital Pharmacist, Lahore	Member
5.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratories, Islamabad	Member
6.	Dr. Amanullah Khan, Director, Drugs Testing Laboratory, Quetta. Government of Balochistan	Member
7.	Dr. Muhammad Khalid Jawed, Director, Drugs Testing Laboratory,Peshawar Government of Khyber Pakhtunkhwa	Member
8.	Mr. Muhammad Hafeez ur Rehman, Deputy Drug Controller, Drugs Testing Laboratory, Rawalpindi Government of the Punjab	Member
9.	Mr. Muhammad Aslam, Deputy Draftsman-II, Representative of Ministry of Law & Justice, Islamabad	Member
10.	Ch. Zeeshan Nazir, Additional Director, Representative of Biological Evaluation & Research Division, DRAP	Member
11.	Dr. Hafsa Karam Ellahi, Additional Director, Representative of QA&LT Division, DRAP	Member
12.	Mr. Abdullah, Additional Director (PE&R), DRAP.	Member/ Secretary
13.	Dr. Muhammad Akram, Dy.Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad	Co-Opted Member

Mr. Asif Jalil, Incharge PEC and respective Assistant Directors, presented the agenda of PE&R Division. Additional Director, BE&R assisted by respective Assistant Directors to present the agenda of Biological Evaluation & Research Division. Additional Director, QA&LT was assisted by respective Assistant Directors to present the agenda of QA & LT Division.

Mr.Tauqeer Ul Haq, Mr.Iftikhar Hussain & Mr. Nawaz Ahmad (PPMA) and Mr. Nadeem Alamgir & Mr.Zia Anwar (Pharma Bureau) and Mr. Khalid Saeed (PC&DA) attended the meeting as observers.

Item No. I: Confirmation of Minutes of 295th Meeting of Registration Board.

295th meeting of Registration Board was held on 08th to 11th June, 2020. Initially draft partial minutes regarding "Favipiravir cases related to Covid-19 management" of Pharmaceutical Evaluation Cell, PE&R Division were distributed among the members of Registration Board on 12th June, 2020 with the request for perusal/approval till 13th June, 2020. All members agreed draft partial minutes. Accordingly, fair partial minutes were approved by Chairman, Registration Board and circulated for implementation.

After that, complete draft minutes were distributed among the members of Registration Board on 17th July, 2020 with the request for perusal/approval/comments (if any) within five days. None of the members disagreed draft minutes. However, Dr. Amanullah Khan, Director, DTL, Quetta responded for correction in the decision of Case No.07 of Post Registration-I Section, PE&R Division as detailed under:

The comments and response is hereby tabulated for information of Board as under: -

Response of Dr. Amanullah Khan	Action Taken
The case of Bayer was discussed in the meeting and it was decided that the change of contract manufacturer is allowed but the contract period with Nabi Qasim will be till the end of previous contract date. In the recorded minutes it is mentioned that case was deferred due to two reasons as mentioned below **a- Complete submission of document as per Form 5F.** **b- Existing status of validity of contract manufacturer.** The case presented shows in point (i) that the firm submitted Form 5F with Rs.50000/- fee. The table of the case in column 5 shows validity of current manufacturer till June 30, 2020.	a. Application was found deficient as per Form-5F which was deferred for submission of complete documents as per Form-5F. b. However, the existing status of contract manufacturer was confirmed and the decision was corrected, accordingly.

The complete minutes in fair, along with comments and response prepared were submitted before Chairman Registration Board for perusal/approval. The Chairman Registration Board after perusal of comments and response approved the complete fair minutes. The same were circulated to concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 295th meeting.

Item No. II **Division of Pharmaceutical Evaluation & Registration**

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Farooq	**Evaluator PEC-I**
2.	Mr. Ammar Ashraf Awan	**Evaluator PEC-II**
3.	Mr. Muhammad Haseeb Tariq	**Evaluator PEC-III**
4.	Mst.Farzana Raja	**Evaluator PEC-IV**
5.	Mst. Iqra Aftab	**Evaluator PEC-V**
6.	Mr. Muhammad Umar Latif	**Evaluator PEC-VI**
7.	Mst. Sidra Khalid	**Evaluator PEC-VII**
8.	Mst. Haleema Sharif	**Evaluator PEC-VIII**
9.	Mst. Saima Hussain	**Evaluator PEC-X**
10.	Mr. Haneef Ullah	**Evaluator PEC-IX**
11.	Mr. Farhadullah	**Evaluator PEC-XI**
12.	Mst. Mehwish Javed Khan	**Evaluator PEC-XIII**
13.	Mr. Muhammad Ahsan Hafiz	**Evaluator PEC-XIV**

Case No. 1: REQUIREMENT OF WHO QOS-PD TEMPLATE FOR INNOVATOR PRODUCTS

Form 5-F (Common Technical Document) was promulgated vide S.R.O 713 (I)/2018 on 8th June, 2018 comprising of following 5 modules:

- Module I: Administrative Part
- Module II: Overviews & Summaries
- Module III: Quality/CMC
- Module IV: Non-clinical/Safety
- Module V: Clinical/Efficacy

In Form 5-F Section 2.3 (Quality Overall Summary) of Module II bears annotation with following statement:

"***QOS has been explained by a WHO QOS-PD template Module 2.3***".

In context of the above referred annotation Registration Board approved the explanatory notes for Form 5F where in details for section 2.3 has been extracted from WHO QOS PD template.

Situation:

Many pharmaceutical firms importing innovator's products submitted that the QOS (Quality Overall Summary) format adopted by DRAP for the Form 5-F is based upon the WHO QOS – product dossiers (QOS-PD) template, intended for multisource (generic) pharmaceutical products containing APIs of synthetic or semi-synthetic origin. This format is adopted both for innovator new drugs as well as for generic drugs by DRAP.

Since the QOS Format mentioned above is for generic version of the drugs; therefore, availability of WHO QOS for innovator brands is not possible to be developed by the parent companies. Due to this challenge, applications for new registration & Post Registration variations (requiring complete dossier) of innovator brands are pending evaluation/processing. This challenge not only resulting in depriving the patients of the benefit of new treatment options but also threatening continued availability of registered innovator products.

To resolve the challenge, it is proposed by Pharma Bureau that "For Innovator/ New drugs (both for Pharmaceutical & Biological drugs) DRAP may accept QOS format for the form 5-F as per ICH M4 Q (R1) guidelines".

The ICH M4Q (R1) format for QOS is an internationally acknowledged and accepted format for filing of NDA and our reference SRAs are practicing the same. All our dossiers of innovator drugs received from our parent companies contains the QOS formats based on ICH M4 (R1).

COMPARISON OF WHO & ICH:

The ICH & WHO narrates similar sort of data requirement but the only difference between WHO PD template and the ICH M4Q (R1) guidelines is that ICH guidelines only describes the requisite information while referring to the Module 3, whereas the WHO PD template specifies the requisite information while providing the sub-sections, tables etc. Few examples are as under:

Section 2.3.S.1 (General Information)	
WHO PD template	**ICH M4Q (R1)**
2.3.S.1.1 Nomenclature *2.3.S.1.2 Structure* *2.3.S.1.3 General Properties*	Information from 3.2.S.1 should be included.
Section 2.3.S.4 Control of the API	
WHO PD template	**ICH M4Q (R1)**
2.3.S.4.1 Specification WHO PD template specifies following table for presentation of information	A brief summary of the justification of the specification(s), the analytical procedures, and validation should be included.

Standard (e.g. Ph.Int., Ph.Eur., BP, USP, in-house)		
Specification reference number and version		
Test	**Acceptance criteria**	**Analytical procedure (Type/Source/Version)**

2.3.S.4.2 Analytical Procedures

2.3.S.4.3 Validation of Analytical Procedures

2.3.S.4.4 Batch Analyses

Summary of batch analyses release results *of the FPP manufacturer* for relevant batches (e.g. comparative bioavailability or biowaiver, stability)

Test	**Acceptance Criteria**	**Results**		
		<batch x>	**<batch y>**	**etc.**
Description				
Identification				
Impurities				
Assay				
etc.				

2.3.S.4.5 Justification of Specification

Specification from 3.2.S.4.1 should be provided.

A tabulated summary of the batch analyses from 3.2.S.4.4, with graphical representation where appropriate, should be provided.

Section 2.3.P.1 Description and Composition of the FPP

WHO PD template	**ICH M4Q (R1)**
The WHO template further gives breakup of requisite information in sub-sections and a table for the presentation of composition is also given. (a) Description of the FPP (in signed specifications): (b) Composition of the FPP. (c) Description of accompanying reconstitution diluent(s), if applicable: (d) Type of container closure system used for the FPP and accompanying reconstitution diluent, if applicable:	Information from 3.2.P.1 should be provided. Composition from 3.2.P.1 should be provided.

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**					
		Quant. per unit or per mL	**%**	**Quant. per unit or per mL**	**%**	**Quantity per unit or per mL**	**%**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>							
Subtotal 1							
<complete with appropriate title e.g. Film-coating >							
Subtotal 2							
Total							

2.3.P.3 Manufacture

WHO PD template	**ICH M4Q (R1)**

<table>
<tr>
<td>2.3.P.3.1 Manufacturer
2.3.P.3.2 Batch Formula
2.3.P.3.3 Description of Manufacturing Process and Process Controls
2.3.P.3.4 Controls of Critical Steps and Intermediates
<table>
<tr><th>Step
(e.g. granulation, compression, coating)</th><th>Controls
(parameters/limits/frequency of testing)</th></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table>
2.3.P.3.5 Process Validation and/or Evaluation</td>
<td>Information from 3.2.P.3 should include: Information on the manufacturer. A brief description of the manufacturing process and the controls that are intended to result in the routine and consistent production of product of appropriate quality. A flow diagram, as provided under 3.2.P.3.3. A brief description of the process validation and/or evaluation, as described in 3.2.P.3.5.</td>
</tr>
</table>

PRACTICES OF VARIOUS REFERENCE REGULATORY AUTHORITIES

1. USFDA:

USFDA is accepting QOS as per the ICH M4Q guidelines for the innovator as well as generic drugs. However FDA has recommended using question based review while developing the QOS document.

1. FDA has published a document titled "A Regulatory Perspective on the Quality Overall Summary: Putting the Pieces Together" (accessed from https://www.fda.gov/media/110657/download on 21st August 2020). Within this document FDA has made the following observations which are produced below:

   "One approach to make the QOS more effective is the use of a question-based review (QbR) QOS for the assessment of ANDAs,"

   "In some ways, the lack of harmonization of regulatory expectations for the QOS across different regions of the world has contributed to its underutilization as an effective application assessment tool. Indeed, a proposal on the QOS was endorsed by the U.S. Food and Drug Administration (FDA) as a top quality-related topic at the ICH Assembly Meeting held in June 2017."

   "It is very important to note that the QOS, in any form, does not replace or change the expected content in Module 3."

   "While the QOS has been helpful in communicating certain quality information, there are opportunities to improve its overall effectiveness. Indeed, one such approach to improving its effectiveness has been the question-based review (QbR) for the Chemistry, Manufacturing, and Controls (CMC) evaluation of ANDAs, which focuses on critical pharmaceutical quality attributes."

   "Other applicants, particularly in the new drug space, have realized the potential to improve the effectiveness of their QOS."

   "One adaptation of the QOS has been the QbR-formatted QOS for ANDA assessment, which applicants may continue to use for their submissions."

   "However, FDA is aware of, and is generally open to, other QOS options that are compliant with ICH M4Q."

   "Again, it is important to note that any QOS framework will negate neither the need for a Module 3 nor the regulator's responsibility to examine Module 3."

2. Office of the generic drugs QbR quality overall summary outline (available at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/office-generic-drugs-qbr-quality-overall-summary-outline. accessed on 25-08-2020) contains the template for QOS which is based on question based review and is different from the ICH template. This template has endorsed certain questions against each heading in the QOS template. But this template is generally for use in generic drugs.
3. Example of Quality overall summary document available at FDA website for the product Ersatzine Tablets is also based on QbD approach.

2. European Medicine Agency (EMA):

European Medicine Agency (EMA), has adopted the QOS as specified in ICH M4Q guidelines. EMA is accepting the QOS on same format for both generic as well as innovator drugs.

3. Medicines and Healthcare products Regulatory Agency (MHRA):
Medicines and Healthcare products Regulatory Agency (MHRA), has adopted the QOS as specified in ICH M4Q guidelines. EMA is accepting the QOS on same format for both generic as well as innovator drugs.

4. Therapeutic Goods Administration (TGA):
Therapeutic Goods Administration (TGA), has adopted the QOS as specified in ICH M4Q guidelines. EMA is accepting the QOS on same format for both generic as well as innovator drugs.

5. Health Canada:
Quality Overall Summary - Chemical Entities (New Drug Submissions/Abbreviated New Drug Submissions) (QOS-CE (NDS/ANDS)) document available at Health Canada website (accessed from https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/templates/quality-overall-summary-chemical-entities-new-drug-submissions-abbreviated-ands.html, on 21-08-2020) specifies the format for quality overall summary for both generic as well as innovator drugs. The format specified by Health Canada is exactly similar to that of WHO QOS-PD template. This template is recommended for both new as well as generic drugs.

6. Pharmaceuticals and Medical Devices Agency (PMDA):
Quality Overall Summary Mock P2 (Description Examples) document for Sakura Tablet available on PMDA website specifies the QOS template for drug product part. The available template contains more specified information as required in ICH guidelines. Although this template is not as per WHO template but still this template has more sub headings and questions as compared to ICH document.

Proceedings:
Registration Board discussed the matter in detail and also reviewed the practices of accepting QOS template of various reference regulatory authorities. Registration Board deliberated that WHO QOS PD template describes the requisite information in a more precise manner, minimizing the chances of disparity between the applicants and regulators. The same is also explained by the ICH QOS document. It was further discussed that WHO QOS-PD template does not require any data which is not already presented in module

Decision: **Keeping in view regulatory practices adopted by various reference regulatory authorities; Registration Board decided also to accept section 2.3 Quality Overall Summary (QOS) of Module 2 of Form 5-F (CTD) as per ICH template for the Innovator products only. Now the applicant of innovator drug product may submit QOS either on WHO QOS-PD template or as per ICH template.**

Case No. 02: PRIORITY REGISTRATION OF REMDESIVIR CONTAINING DRUG PRODUCTS

Background:

Keeping in view the current outbreak of Covid-19, the Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 decided as under for priority registration of Remdesivir containing drug products:

> ***Authority, exercising its power under Rule 26 of Drugs (LRA) Rules amended via SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F, for Registration of Remdesivir and Tocilizumab in light of approvals granted by the reference regulatory authorities and with the following additional conditions:***
>
> ***a. The applicants can submit their applications till 31-07-2020 and these applications will be considered out of queue.***
> ***b. Registration Board shall consider grant of registration under proviso of Rules 29(6) (8) of the Drug (Licensing, Registration & Advertising) Rules, 1976 and shall follow precautions / terms & conditions as adopted by the Reference Regulatory Authorities.***
> ***c. The registration holders including those granted registration under Form 5D as a new drug will submit data of product development and 6 months accelerated and 6 months real time stability studies data within one year along with other data as may be required by Registration Board. The data will be considered by Registration Board for further decision.***

Consequently, Registration Board in its 295th meeting held on 8th to 11th June, 2020 granted registration of Remdesivir (emergency use authorization) to 12 firms under section 7 of the Drugs Act, 1976 and rule 29 (6) (8) of Drugs (Licensing, Registering and Advertising) Rules, 1976 with same precautions/ terms and conditions as adopted by Reference Regulatory Authorities.

In this regard, Registration Board also specified following condition among a number of other conditions subject to which the registrations were approved:

> **"Firm will report monthly to National Pharmacovigilance Centre, Pharmacy Services Division DRAP, serious adverse events and all medication errors associated with the use of the authorized Remdesivir that are reported to the firm during the pandemic."**

Pharmacy Services Division was accordingly requested to collect & compile data regarding serious adverse events and all medication errors associated with the use of Remdesivir from all firms which have been granted registration of Remdesivir (emergency use authorization) for consideration by the Registration Board in its 296th meeting of Registration Board, scheduled on 08th September, 2020.

In response, Pharmacy Services Division has informed (vide letters dated 11-08-2020 & 21-08-2020) that following firms have been directed to comply with the above mentioned decision of Registration Board. The firms have also been advised to make a proper pharmacovigilance system in their organization by upgrading and strengthening the procedures of collection and monitoring of adverse drug reactions from patients and healthcare professionals.

1. M/s BF Biosciences Ltd *(Nil report from 1st to 26th August, 2020)*
2. M/s Bio Labs Pvt Ltd. *(Nil Report in July and August 2020)*
3. M/s Allmed Pvt Ltd. *(Not marketing)*
4. M/s Nabiqasim Industries Pvt Ltd. *(Nil Report from July to August, 2020)*
5. M/s Bosch Pharmaceuticals (Pvt.) Ltd. *(1st July to 1st September, 2020)*
6. M/s Sami Pharmaceuticals (Pvt) Limited *(Nil Report for August, 2020)*
7. M/s Macter International Limited *(under manufacturing not yet marketing)*
8. M/s Hilton Pharma Pvt Ltd. *(not yet Marketing)*
9. M/s. Winsfeild Pharmaceuticals *(Nil Report August, 2020)*
10. M/s The Searle Company Limited *(Nil report August, 2020)*
11. M/s OBS Healthcare (Pvt) Limited, *(Nil Report June, 2020*)

Current Situation

Registration Board was apprised of the decision of Authority taken in its 91st meeting held on 4th September, 2020 regarding registration of Remdesivir containing drug products as under:

> ***"The Authority keeping in view the status of emergency use authorization of Remdesivir in reference regulatory authorities, prevailing situation of COVID-19 and for preparedness of any emergency situation in the country, advised the Registration Board to proceed in the matter on following analogies:***
>
> ***I. Consider new registration applications of Remdesivir after submission of following:***
>
> ***i. Product development data and 3 months accelerated and real time stability studies data for zone IV-A***
>
> ***ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division.***

II. For already granted registrations for emergency use authorization, firms shall be advised to submit:

i. Product development data and 3 months accelerated and real time stability studies data for zone IV-A

ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division within two weeks.

III. Registrations of emergency use authorizations of Remdesivir, not complying with above conditions will be suspended till the submission of requisite data and approval by Registration Board.

The Authority further decided not to extend the exemption date under SRO 713(I)/2018."

The Board deliberated upon the above cited decision of the Authority and decided as under for further processing of the Registration applications of Remdesivir containing drug products.

- All new registration applications of Remdesivir will be considered upon submission of following:
  i. Product development data and 3 months accelerated and real time stability studies data for Zone IV-A
  ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division.
- For already granted registrations for emergency use authorization, firms shall be advised to submit:
  i. Product development data and 3 months accelerated and real time stability studies data for Zone IV-A
  ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division within two weeks.
- Registrations of emergency use authorizations of Remdesivir, not complying with above conditions will be suspended till submission of requisite data and approval by Registration Board.

Proceedings & Decision:

As requisite data has not been submitted by any of the applicant, thus Registration Board decided to defer following applications for "Remdesivir" for submission of following data:

i. Product development data and 3 months accelerated and real time stability studies data for Zone IV-A
ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division.

I. Applications of Local manufacturing:

1.	Name and address of Manufacturer / Applicant	M/s Welwrd Pharmaceuticals.Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name+DosageForm+Strength	Remvir 5mg/ml Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13116; 09-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
2.	Name and address of Manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Hattar
	Brand Name+DosageForm+Strength	Remvid Lyophilized Powder for Injection 100mg
	Composition	Each Vial contains: Remdesivir Lyophilized Sterile Powder ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13181; 09-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As per SRO
3.	Name and address of Manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name+DosageForm+Strength	Remdisil Liquid Solution for Infusion
	Composition	Each 20ml vial contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy. No.13659; 15-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D

	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
4.	Name and address of Manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Biovir Injection 5mg/ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13664; 15-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
5.	Name and address of Manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore
	Brand Name+DosageForm+Strength	Remi Injectable Solution 100mg/ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13661; 15-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
6.	Name and address of Manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi
	Brand Name+DosageForm+Strength	Redesvir 100 Injection
	Composition	Each Lyophilized vial contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14133; 19-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
7.	Name and address of Manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi
	Brand Name+DosageForm+Strength	Redesvir Liquid solution for Injection 5mg/ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14134; 18-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
8.	Name and address of Manufacturer / Applicant	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Macdevir 100mg/20ml Liquid Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14131; 18-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
9.	Name and address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name+DosageForm+Strength	Remitec Injection 100mg/20ml
	Composition	Each Vial (20ml) contains :

		Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14852; 25-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
10.	Name and address of Manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu
	Brand Name+DosageForm+Strength	Tamcor 100mg/2ml Liquid solution for Infusion
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14743; 24-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
11.	Name and address of Manufacturer / Applicant	M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi
	Brand Name+DosageForm+Strength	Remidi concentrated solution for infusion 5mg/ml
	Composition	Each ml contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14514; 23-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
12.	Name and address of Manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name+DosageForm+Strength	Remvir Injection 5mg/ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14742; 24-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
13.	Name and address of Manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name+DosageForm+Strength	Remiv Injection 100mg
	Composition	Each lyophilized Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.15770; 01-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
14.	Name and address of Manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore
	Brand Name+DosageForm+Strength	Medvir-19 Injection 100mg/2ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13765; 16-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO

15.	Name and address of Manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore
	Brand Name+DosageForm+Strength	Medvir-19 Injection 100mg/2ml
	Composition	Each Vial contains : Remdesivir lyophilized powder eq to Remdisvir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13764; 16-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
16.	Name and address of Manufacturer / Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Remsivir Injection 100mg/2ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 80mg
	Diary No. Date of R&I & fee	Dy. No.14226; 19-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
17.	Name and address of Manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name+DosageForm+Strength	Covizaf Concentrated solution for infusion 100mg/20ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14223; 19-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
18.	Name and address of Manufacturer / Applicant	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Remdisave 5mg/ml Infusion
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14356; 22-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
19.	Name and address of Manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name+DosageForm+Strength	Remvir 100mg/20ml Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14355; 22-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
20.	Name and address of Manufacturer / Applicant	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name+DosageForm+Strength	Codesvir 100mg/20ml Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.15174; 29-06-2020 ; Rs.20,000

	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
21.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Brand Name+DosageForm+Strength	Remz Injection 100mg
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14740; 24-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
22.	Name and address of Manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Remdesivir 100mg/20ml Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13774; 16-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
23.	Name and address of Manufacturer / Applicant	M/s Hamaz Pharmaceuticals Pvt Ltd. Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan
	Brand Name+DosageForm+Strength	Covirid Concetrated solution for infusion 100mg
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14745; 24-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
24.	Name and address of Manufacturer / Applicant	M/s GT Pharma Pvt Ltd. Plot No. 713, Sundar Industrial Estate, Lahore
	Brand Name+DosageForm+Strength	Remend Concentrated for Solution for Infusion
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17307; 16-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO
25.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name+DosageForm+Strength	Saferemid Injection 100mg/20ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.15619; 01-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO

26.	Name and address of Manufacturer / Applicant	M/s Friends Pharma Pvt Ltd. 31-km, Ferozepur Road, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Simdesivir Injection 100mg
	Composition	Each Lyophilized Vial Contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.16257; 07-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As per SRO
27.	Name and address of Manufacturer / Applicant	M/s Friends Pharma Pvt Ltd.31-km, Ferozepur Road, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Simdesivir Solution for Injection 100mg/20ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.16258; 07-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As per SRO
28.	Name and address of Manufacturer / Applicant	M/s Bosch Pharmaceuticals Pvt Ltd. Plot No. 209, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Remivir 100mg/20ml Liquid Injectable
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.16159; 07-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
29.	Name and address of Manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Besivir 100mg/20ml Liquid Injectable
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.16160; 07-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
30.	Name and address of Manufacturer / Applicant	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Rememac 100mg/20ml Lyophilized for Injection
	Composition	Each ml contains : Remdesivir ….. 5mg
	Diary No. Date of R&I & fee	Dy. No.15703; 02-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
31.	Name and address of Manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Remdisol Injection 5mg/ml
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17304; 16-07-2020 ; Rs.50,000

	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Pharmasol's Specs
	Pack Size & Demanded Price	As per SRO
32.	Name and address of Manufacturer / Applicant	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remedy Injection 100mg/20ml
	Composition	Each 20ml Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17062; 14-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	EG Specs
	Pack Size & Demanded Price	As per SRO
33.	Name and address of Manufacturer / Applicant	M/s Hygeia Pharmaceuticals. Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Hydesivir Injection 100mg/20ml
	Composition	Each 20ml Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17160; 15-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Hygeia Specs
	Pack Size & Demanded Price	As per SRO
34.	Name and address of Manufacturer / Applicant	M/s Mediceena Pharma. 27 Km, Raiwind Road, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Remdicina Lyophilized Powder for Infusion
	Composition	Each Lyophilized Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17874; 22-07-2020 ; Rs.100,000
	Pharmacological Group	Investigational
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per Pricing Policy
35.	Name and address of Manufacturer / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name+DosageForm+Strength	Desvir 100mg/20ml Solution for Injection
	Composition	Each Vial(20ml) contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17715; 21-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO
36.	Name and address of Manufacturer / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name+DosageForm+Strength	Genvir 100mg Injection I.V
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17716; 22-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO

37.	Name and address of Manufacturer / Applicant	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.
	Brand Name+DosageForm+Strength	Remvir 100mg/20ml Injection
	Composition	Each 20ml Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.18212; 24-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO
38.	Name and address of Manufacturer / Applicant	M/s Lawrence Pharma Pvt. Ltd. 10.5 Km, Sheikhupura Road, Lahore
	Brand Name+DosageForm+Strength	Lemdesivir Injection
	Composition	Each 1ml contains : Remdesivir …5mg
	Diary No. Date of R&I & fee	Dy. No.18210; 24-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	
	Pack Size & Demanded Price	As Per SRO
39.	Name and address of Manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name+DosageForm+Strength	Romafer 100mg/20ml IV Injection for Soultion
	Composition	Each Vial contains : Remdesivir…5mg
	Diary No. Date of R&I & fee	Dy. No.18693; 29-07-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per DRAP Policy
40.	Name and address of Manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name+DosageForm+Strength	Remitor Injection
	Composition	Each 20ml Vial contains : Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy. No.18760; 30-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per DRAP Pricing Policy
41.	Name and address of Manufacturer / Applicant	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore
	Brand Name+DosageForm+Strength	Remdi Injection
	Composition	Each ml contains : Remdesivir…5mg
	Diary No. Date of R&I & fee	Dy. No.18770; 30-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per DRAP Pricing Policy
42.	Name and address of Manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Desmer 100mg/20ml Injection
	Composition	Each Vial contains : Remdesivir…100mg/20ml
	Diary No. Date of R&I & fee	Dy. No.15450; 30-06-2020 ; Rs.20,000

	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Trigon Specifications
	Pack Size & Demanded Price	As Per DRAP Pricing Policy
43.	Name and address of Manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi
	Brand Name+DosageForm+Strength	Covizaf Lyophillized Powder for Injection 100mg
	Composition	Each Vial contains : Remdesivir Lyophilized Powder for Injection …100mg
	Diary No. Date of R&I & fee	Dy. No.15451; 30-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per PRC
44.	Name and address of Manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name+DosageForm+Strength	Indorem 5mg/ml Injection
	Composition	Each ml contains : Remdesivir…5mg
	Diary No. Date of R&I & fee	Dy. No.15444; 30-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per SRO
45.	Name and address of Manufacturer / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore
	Brand Name+DosageForm+Strength	DV-Rem 100mg/20ml Injectable Solution
	Composition	Each 20ml Vial contains : Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy. No.15446; 30-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	As Per SRO

II. Applications of local manufacturing by way of contract manufacture:

46.	Name and address of Manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore By: M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Remi Lyophilized Powder for Injection
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.15176; 29-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
47.	Name and address of Manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi By: M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	IIndorem 100mg Injection
	Composition	Each Vial contains : Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy. No.15445; 30-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral

	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	As Per DRAP Pricing Policy
48.	Name and address of Manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Hattar By M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name+DosageForm+Strength	Remedi Injection 5mg/ml
	Composition	Each Vial (20ml) contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13180; 09-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
49.	Name and address of Manufacturer / Applicant	M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remdesivir Injection 5mg/ml
	Composition	Each 20ml contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17571; 20-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Bio Lab's Specifications
	Pack Size & Demanded Price	As Recommended by PRC
50.	Name and address of Manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore By: M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Genvir 5mg/ml Concentrated Solution for Infusion
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.18314; 27-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per relevent SRO

III. Applications of Import:

51.	Name and address of Manufacturer / Applicant	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa By: M/s Hetero Labs Limited. 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad-500018, Telangana, India
	Brand Name+DosageForm+Strength	Civifor 100mg Lyophilized Powder for Concentrate for Solution for Infusion
	Composition	Each Lyophilized Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17712; 21-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	
	Pack Size & Demanded Price	As Per SRO

52.	Name and address of Manufacturer / Applicant	M/s AGP Limited. B-23-C, S.I.T.E. Karachi By: M/s Mylan Laboratories Limited. No. 19-A, Plot No. 284/B1 Bommasandra-Jigani Link Road, Industrial Area, Anekal Taluk Banglore- 560 105, India
	Brand Name+DosageForm+Strength	Desrem Lyophilized Powder for Infusion
	Composition	Each Lyophilized Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.18214; 24-07-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	
	Pack Size & Demanded Price	As Per approved SRO/ MRP: Rs. 10,873/-
53.	Name and address of Manufacturer / Applicant	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700 By: M/s Healthcare Pharmaceutical Ltd. Gazariapara, Rajendrapur, Gazipur-1703, Bangladesh
	Brand Name+DosageForm+Strength	Remdevir Injection 100mg
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17161; 15-07-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO
54.	Name and address of Manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi. By: M/s Eskayef Pharmaceutical Ltd. 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh
	Brand Name+DosageForm+Strength	Remivir 100mg Lyophilized Powder for Injection
	Composition	Each Vial contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.17306; 16-07-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As fixed by DPC
55.	Name and address of Manufacturer / Applicant	M/s Himmel Pharmaceuticals Pvt Ltd. 793-D Block C, Faisal Town, Lahore, Pakistan By: M/s Beacon Pharmaceuticals Limited.Kathali, Bhaluka, Mymensingh, Bangladesh
	Brand Name+DosageForm+Strength	Pandovir 100 IV Injection
	Composition	Each vial Lyophilized powder for solution for infusion contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.14512; 23-06-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
56.	Name and address of Manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name+DosageForm+Strength	Adremid Injection 100mg/20ml
	Composition	Each Vial (20ml) contains : Remdesivir …….. 100mg
	Diary No. Date of R&I & fee	Dy. No.15618; 01-07-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5

	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
57.	Name and address of Manufacturer Applicant	M/s AJM Pharma. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan By: M/s Eva Pharma of Pharmaceuticals and Medical Appliances. Kafr El Gabal, El Haram, Giza, Egypt
	Brand Name+DosageForm+Strength	Ajvir 100mg/20ml Concentrate for solution for IV Infusion
	Composition	Each 20ml contains : Remdesivir …100mg
	Diary No. Date of R&I & fee	Dy. No.18690; 29-07-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	
	Pack Size & Demanded Price	As Per SRO

- For already granted registrations for emergency use authorization, firms shall be advised to submit:
  i. Product development data and 3 months accelerated & real time stability studies data for Zone IV-A.
  ii. Protocols of Pharmacovigilance data submission duly endorsed by Pharmacy Services Division within two weeks.

Registrations of emergency use authorizations of Remdesivir, not complying with above conditions will be suspended till the submission of requisite data and approval by Registration Board.

Case No. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

58.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd, Plot # FD-46-A-8, Street-I Sector-38, Korangi Creek Industrial Park, Karachi Pakistan Contract Manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ncopenem 500mg Injection (IV)
	Composition	Each Vial Contains: Meropenem as Trihydrate Blended with Anhydrous Sodium Carbonate (Sterial)…500mg
	Diary No. Date of R& I & fee	Dy.No 44463 dated 31-12-2018 Rs.50,000/-
	Pharmacological Group	Carbapenem
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meropenem 500 mg Powder for Solution for Injection or Infusion by M/s Hospira UK Limited (MHRA Approved)
	Me-too status	Meronem by ICI Pakistan (Reg. No. 018543),
	GMP status	cGMP certificate issued based on the evaluation conducted on 28-1-2020.
	Remarks of the Evaluator.(VI)	The firm has carbapenem section according to the cGMP certificate. M/s Palpex Pharmaceutical has not previously applied product for contract manufacturing and it has 7 sections.
	Decision: Deferred for capacity assessment of Nicholas Pharmaceuticals.	
59.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd, Plot # FD-46-A-8, Street-I Sector-38, Korangi Creek Industrial Park, Karachi Pakistan Contract Manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ncopenem 1g Injection (IV)
	Composition	Each Vial Contains: Meropenem as Trihydrate Blended with Anhydrous Sodium Carbonate (Sterial)…1gm
	Diary No. Date of R& I & fee	Dy.No 44462 dated 31-12-2018 Rs.50,000/-
	Pharmacological Group	Carbapenem
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meronem 1g by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Meronem by ICI Pakistan (Reg. No. 018548)
	GMP status	cGMP certificate issued based on the evaluation conducted on 28-1-2020.
	Remarks of the Evaluator.(VI)	The firm has carbapenem section according to the cGMP certificate. M/s Palpex Pharmaceutical has not previously applied product for contract manufacturing and it has 7 sections.
	Decision: Deferred for capacity assessment of Nicholas Pharmaceuticals.	
60.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd, Plot # FD-46-A-8, Street-I Sector-38, Korangi Creek Industrial Park, Karachi Pakistan Contract Manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ertapem 1g Injection (IV)
	Composition	Each Vial Contains: Ertapenem sodium eq to ertapenem….1gm
	Diary No. Date of R& I & fee	Dy.No 44461 dated 31-12-2018 Rs.50,000/-
	Pharmacological Group	Carbapenem

	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved; ERTAPENEM 1G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
	Me-too status	Invanz by Muller & Phipps (Reg. No. 043051)
	GMP status	cGMP certificate issued based on the evaluation conducted on 28-1-2020.
	Remarks of the Evaluator.(VI)	The firm has carbapenem section according to the cGMP certificate. M/s Palpex Pharmaceutical has not previously applied product for contract manufacturing and it has 7 sections.
	Decision: Deferred for capacity assessment of Nicholas Pharmaceuticals.	
61.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd, Plot # FD-46-A-8, Street-I Sector-38, Korangi Creek Industrial Park, Karachi Pakistan Contract Manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cilasten 250mg Injection (IV)
	Composition	Each Vial Contains: Imipenem ……..250mg Cilastatin sodium eq to cilastatin….250mg
	Diary No. Date of R& I & fee	Dy.No 44464 dated 31-12-2018 Rs.50,000/-
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Imipenem/Cilastatin 250mg/250mg Powder for Solution for Infusion by M/s Actavis Group PTC ehf (MHRA Approved)
	Me-too status	Cilapen by Bosch (Reg No. 048490)
	GMP status	cGMP certificate issued based on the evaluation conducted on 28-1-2020.
	Remarks of the Evaluator.(VI)	The firm has carbapenem section according to the cGMP certificate. M/s Palpex Pharmaceutical has not previously applied product for contract manufacturing and it has 7 sections.
	Decision: Deferred for capacity assessment of Nicholas Pharmaceuticals.	
62.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd, Plot # FD-46-A-8, Street-I Sector-38, Korangi Creek Industrial Park, Karachi Pakistan Contract Manufacturing from M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cilasten 500mg Injection (IV)
	Composition	Each Vial Contains: Imipenem …..500mg Cilastatin sodium eq to cilastatin….500mg
	Diary No. Date of R& I & fee	Dy.No 44465 dated 31-12-2018 Rs.50,000/-
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Imipenem/Cilastatin 500 mg/500 mg, powder for solution for infusion b M/s Fresenius Kabi Ltd (MHRA Approved)
	Me-too status	Primaxin by Stallion (Reg No. 080839)
	GMP status	cGMP certificate issued based on the evaluation conducted on 28-1-2020.

	Remarks of the Evaluator.(VI)	The firm has carbapenem section according to the cGMP certificate. M/s Palpex Pharmaceutical has not previously applied product for contract manufacturing and it has 7 sections.
	Decision: Deferred for capacity assessment of Nicholas Pharmaceuticals.	
63.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medpectam Injection 500mg
	Composition	Each Vial Contains: Cefoperazone Sodium…250mg Sulbactam Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 15925 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	2Sum Injection 500mg of M/s Sami Pharmaceuticals, Karachi (Reg.# 079941)
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
64.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab.28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medpectam Injection 1000mg
	Composition	Each Vial Contains: Cefoperazone Sodium…500mg Sulbactam Sodium…500mg
	Diary No. Date of R& I & fee	Dy.No 15926 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection by Pfizer Inc. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
65.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab.28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medpectam Injection 2000mg
	Composition	Each Vial Contains: Cefoperazone Sodium…1000mg Sulbactam Sodium……..1000mg
	Diary No. Date of R& I & fee	Dy.No 15927 dated 07-03-2019 Rs.50,000/- 06-03-2019

	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
66.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab.28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Mediximе DS 100mg/5ml suspension
	Composition	Each 5ml contains: Cefixime as Trihydrate…100mg
	Diary No. Date of R& I & fee	Dy.No 153931 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stlicef Dry Suspension 100mg/5ml of Treat Pharma
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
67.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Mediximе DS 200mg/5ml suspension
	Composition	Each 5ml contains: Cefixime as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 153932 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stlicef Dry Suspension 200mg/5ml of Treat Pharma
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
68.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt

		Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medixime Capsule 400mg
	Composition	Each capsule contains: Cefixime Trihydrate…400mg
	Diary No. Date of R& I & fee	Dy.No 15928 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Spanix Capsule by Neomedix Pharma
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension, capsule (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
69.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medipim Injection 1000mg
	Composition	Each Vial Contains: Cefepime as Hcl …1000mg
	Diary No. Date of R& I & fee	Dy.No 15921 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuxipim 1g Injection of Bosch
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
70.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medipim Injection 500mg
	Composition	Each Vial Contains: Cefepime as Hcl …500mg
	Diary No. Date of R& I & fee	Dy.No 15921 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nuxipim 500mg Injection of Bosch

	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
71.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medadin Injection 500mg
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 15923 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ceftaz by Pharmedic
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
72.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medadin Injection 250mg
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 15992 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ceftaz by Pharmedic
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
73.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medodoxime DS 50mg/5ml suspension
	Composition	Each 5ml contains: Cefpodoxime as Proxetil…50mg
	Diary No. Date of R& I & fee	Dy.No 15929 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
74.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medodoxime DS 100mg/5ml suspension
	Composition	Each 5ml contains: Cefpodoxime as Proxetil…100mg
	Diary No. Date of R& I & fee	Dy.No 15930 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	
75.	Name and address of manufacturer / Applicant	M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt Contract manufacturing from M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Cefamed Injection 250mg IM
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 15930 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Cephlosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP status	M/s Medpharm research Lab Lahore:- Panel inspection for renewal of DML dated 22-1-2018Overall evaluation of inspection report is good
	Remarks of the Evaluator.(VI)	Medpharm has dry powder injection and suspension (Cephalosporin) section
	Decision: Deferred for consideration on its turn according to the queue.	

b. Deferred cases

76.	Name and address of manufacturer / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name +Dosage Form + Strength	Velanef 800mg Tablets
	Composition	Each Film Coated Tablet Contains: Sevelamer HCL…800mg
	Diary No. Date of R& I & fee	Dy.No 35106 dated 23-10-2018 Rs.20,000/- 22-10-2018
	Pharmacological Group	Phosphate Binder
	Type of Form	Form 5
	Finished product Specification	Mfg
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renagel 800mg Tablet by M/s Genzyme Corporation, (USFDA approved)
	Me-too status	Renavel 800mg Tablet by M/s AllianzeMed Pharmaceuticals (Reg No:075510)
	GMP status	26-10-2018. The firm is not found working as required under the law/rule
	Remarks of the Evaluator. (VI)	
	Previous Decision	Decision of 293rd: Deferred for updated GMP status of the firm from QA&LT Division.
	Evaluation by PEC: The firm has submitted panel inspection report dated 25-11-2019, the panel recommended for the renewal of DML.	
	Decision: Approved with innovator's specification	
77.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24444 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Flostin Tablets
	Composition	Each film coated tablet contains: Fluoxetine as HCl….10mg
	Pharmacological Group	Selective serotonin reuptake inhibitors N06AB03
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2,10,20,30 PVC Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	044602; "Futine 10 mg Tab. "M/s Wilshire Laboratories, 124/A, Kotlakhpat, Indus. Area, Township Scheme, Lahore.
	GMP status	24-06-2019 Decision of the 270th Meeting of CLB: The board after detailed discussion on the investigation report of FID dated 13-05-2019, in the compliance to 267th meeting of CLB, decided to issue show cause notice to the following accused persons and give them opportunity of personal hearing n the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General). I- M/s Pharmedic Laboratories Pvt Ltd, Lahore through its CEO. II- Management of M/s Pharmedic Laboratories Lahore as per Form-29 of SECP. i- Mr Waqar A Sheikh CNIC No 35202-9152354-3 ii- Mr Adeel A Sheikh CNIC No 35202-9143709-3 III- Mr Muhammad Nouman Ahmed, Quality Control Incharge S/O Muhammad Anwar ul Haq, CNIC No. 35202-2745122-9 IV- Mr Jamshaid Ghani, Production Incharge S/O Abdul Ghani, CNIC No 54400-0548981-5

	Remarks of the Evaluator. (VI)	Justification for 3% overage.
	Decision of 291st : Registration Board referred the case to QA & LT Division for updated GMP status of the firm. Evaluation by PEC:The firm has submitted panel Inspection report dated 4-2-2020 satisfactory level of GMP compliance.	
	Decision:Deferred for justification of overage in master formulation.	
78.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24443 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Biofol Dry Suspension
	Composition	Each 5ml contains: Iron as Iron III hydroxide polymaltose complex… 50mg Folic Acid…0.43mg
	Pharmacological Group	Anti-anemic
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60 ml amber color, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	042952; Hemoplex-F Syrup M/s Synchro Pharmaceuticals, Kot Lakhpat, Lahore
	GMP status	24-06-2019: Decision of the 270th Meeting of CLB: The board after detailed discussion on the investigation report of FID dated 13-05-2019, in the compliance to 267th meeting of CLB, decided to issue show cause notice to the following accused persons and give them opportunity of personal hearing in the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General). I- M/s Pharmedic Laboratories Pvt Ltd, Lahore through its CEO. II- Management of M/s Pharmedic Laboratories Lahore as per Form-29 of SECP i- Mr Waqar A Sheikh CNIC No 35202-9152354-3 ii- Mr Adeel A Sheikh CNIC No 35202-9143709-3 III- Mr Muhammad Nouman Ahmed, Quality Control Incharge S/O Muhammad Anwar ul Haq, CNIC No. 35202-2745122-9 IV- Mr Jamshaid Ghani, Production Incharge S/O Abdul Ghani, CNIC No 54400-0548981-5
	Remarks of the Evaluator. (VI)	Evidence of international availability. Section approval certificate Me-too is not confirmed
	Decision of 291st: Registration Board referred the case to QA & LT Division for updated GMP status of the firm. **Evaluation by PEC:** The firm has submitted panel Inspection report dated 4-2-2020 satisfactory level of GMP compliance.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm as referred generic liquid syrup and instant product is dry powder suspension.	
79.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy. No. 134: 22-7-2015, PKR 20, 000/-: 22-07-2015
	Brand Name +Dosage Form + Strength	Lycain 1% Injection
	Composition	Each 5ml ampoule contains: Lidocaine hydrochloride……. 50mg
	Pharmacological Group	Local anesthetic
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	5's: Rs. 12/ampoule
	Approval status of product in Reference Regulatory Authorities.	Lidocaine 1% injection by Accord Healthcare (MHRA Approved)
	Me-too status	Lidocaine injection by Tabros
	GMP status	Last inspection report dated 31-08-2016 confirms satisfactory compliance to GMP
	Remarks of the Evaluator.	Firm has initially applied for 35mg/3.5ml injection and later changed the composition to 50mg/5ml since the formulation was not approved by any reference regulatory authority. **Decision of 273rd** Deferred for submission of fee Rs. 20,000/- since the firm has changed the formulation from 35mg/5ml to 50mg/5ml injection. Firm has submitted the required fee Dated 24-10-2017.
	Decision of 277th: Registration Board deferred the case for submission of latest GMP inspection report conducted within last one year. Board further directed to send a reference to QA & LT Division to conduct GMP inspection of Firm on priority. Evaluation by PEC**(VI)**: The firm has submitted panel Inspection report dated 04-02-2020 showing satisfactory level of GMP compliance.	
	Decision: Approved.	
80.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad
	Diary No. Date of R& I & fee	Dy.No 34703 dated 18-10-2018 Rs.20,000/- Dated 18-10-2018
	Brand Name +Dosage Form + Strength	Gastrocon Suspesnion
	Composition	Each 10ml Contains: Sodium Alginate…500mg Sodium Bicarbonate…267mg
	Pharmacological Group	A02BX, Drugs for pepti ulcer and GERD disease.
	Type of Form	Form 5
	Finished product Specification	Mfg
	Pack size & Demanded Price	120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	26-7-2018, firm is operating at good level of GMP compliance.
	Remarks of the Evaluator.	Product in RRA and me-too could not be confirmed.
	Decision of 293rd : Deferred for following: □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board Evaluation by PEC(VI): The firm has submitted a reference from ANSM of Gaviscon Oral suspension in a bottle and me too status as N-Tasid 500mg/267mg liquid of GETZ pharma Reg no 044339.	
	Decision: Deferred for confirmation of me-too / generic for applied formulation.	
81.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract manufacturing By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Dy.No 35108 dated 23-10-2018 Rs.50,000/- Dated 23-10-2018
	Brand Name +Dosage Form + Strength	DualCef 2gm IV/IM Injection
	Composition	Each Vial Contains: Sterile Powder of Cefoperazone Sodium Eq. to Cefoperazone…1gm Sterile Powder of Sulbactam Sodium Eq. to Sulbactum…1gm
	Pharmacological Group	Cephalosporins

	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.	The firm M/s Saffron Pharmaceuticals, Faisalabad has 5 products already on contract manufacturing.
	Decision of 293rd : Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore **Evaluation by PEC**(VI)**:** The firm has submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing dated 21-04-2020. The Registration Board allowed contract manufacturing from Novamed Pharmaceuticals.	
	Decision: Approved.	
82.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract manufacturing By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Dy.No 35109 dated 23-10-2018 Rs.50,000/- Dated 23-10-2018
	Brand Name +Dosage Form + Strength	DualCef 1gm IV/IM Injection
	Composition	Each Vial Contains: Sterile Powder of Cefoperazone Sodium Eq. to Cefoperazone…500mg Sterile Powder of Sulbactam Sodium Eq. to Sulbactum…500mg
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection by Pfizer Inc. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.	The firm M/s Saffron Pharmaceuticals, Faisalabad has 5 products already on contract manufacturing.
	Decision of 293rd : Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore **Evaluation by PEC**(VI)**:** The firm has submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing dated 21-04-2020. The registration board allowed contract manufacturing from Novamed Pharmaceuticals.	
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract manufacturing By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Dy.No. 36785 dated 06-11-2018 Rs.50,000/-Dated 06-11-2018
	Brand Name +Dosage Form + Strength	DualCef 500mg IV/IM Injection

		Combin NeoSum
	Composition	Each Vial Contains: Sterile Powder of Cefoperazone Sodium Eq. to Cefoperazone…250mg Sterile Powder of Sulbactum Sodium Eq. to Sulbactum…250mg
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved
	Me-too status	Ceflactam Injection 500mg M/s Barret Hodgson
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.	The firm M/s Saffron Pharmaceuticals, Faisalabad has 5 products already on contract manufacturing.
	Decision of 293rd : Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore **Evaluation by PEC**(VI)**:** The firm has submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing dated 21-04-2020. The registration board allowed contract manufacturing from Novamed Pharmaceuticals.	
	Decision: Approved.	
84.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt ltd, 124/1 Industrial Estate, KOt Lakhpat Lahore
	Diary No. Date of R& I & fee	Dy.No. 324 dated 6-07-2011 Rs.8,000/- Dated 6-07-2011, Rs. 12,000 dated 9-01-2015 (Duplicated fee Chalan)
	Brand Name +Dosage Form + Strength	Zimid 30mg Injection Vial
	Composition	Each vial contains: Lansoprazole….30mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specification	Mfg
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA "Prevacid 30mg lsterile lyophilized powder for injection
	Me-too status	Qipro 30mg injection Reg. 015133 by Bosch.
	GMP status	Wilshire: cGMP certificate is granted based on inspection dated 26-9-2017.
	Remarks of the Evaluator.	
	Decision of 295th : Deferred for the confirmation of manufacturing facility of the applied product. Evaluation by PEC(VI): The firm has submitted that they will procure lyophilized powder from manufacturers which it then fills in the vial. We have dry powder injection (General) section.	
	Decision: Deferred for confirmation whether manufactured via lyophilisation or dry powder filling.	
85.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt ltd, 124/1 Industrial Estate, KOt Lakhpat Lahore
	Diary No. Date of R& I & fee	0987, 6-06-2011, 8,000/- 6-6-2011, Rs. 12,000, 14-1-2015 (Duplicate Dossier)
	Brand Name +Dosage Form + Strength	Agitanil 10mg Injection
	Composition	Each vial contains: Olanzapine…..10mg
	Pharmacological Group	Atypical Antipsychotic

	Type of Form	Form 5
	Finished product Specification	Mfg
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate is granted based on inspection dated 26-9-2017.
	Remarks of the Evaluator.	Fee challan photocopy attached.
	Decision of 295th : Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board **Evaluation by PEC**(VI)**:** The firm has submitted Zyprexa 10mg Injection USFDA Approved and me too as Zanzia 10mg Injection Reg No 077089 by English Pharma	
	Decision: Deferred for confirmation whether product will be manufactured by way of lyophilisation or dry powder filling along with scientific details	
86.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22200 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Maxzid 4mg Tablet
	Composition	"Each film coated tablet contains: Tizanidine HCl eq to Tizanidine…4mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX02
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Zanaflex® USFDA Approved.
	Me-too status	080865; "Zinzan 4mg Tablet "Wellborne Pharmachem and Biologicals, Hattar."
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decisionof 292nd : Deferred for evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee. **Evaluation by PEC**(VI)**:** The firm has revised the formulation from film coated to uncoated tablet with the submission of Rs.5,000 (Duplicate/copy) Deposit No1936832.	
	Decision: Approved	
87.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22199 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Maxzid 2mg Tablet
	Composition	"Each film coated tablet contains: Tizanidine HCl eq to Tizanidine…2mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents (M03BX02)
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Zanaflex® USFDA Approved.
	Me-too status	078514 ; Xinasia Tablets Med Asia Pharmaceuticals (Pvt) Ltd., Risalpur
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/ agencies which were declared/ approved by the Registration Board in 275th meeting.
	Decision of 292nd : Deferred for evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee. **Evaluation by PEC**(VI)**:** The firm has revised the formulation from film coated to uncoated tablet with the submission of Rs.5,000 (Duplicate/copy) Deposit No193681.	
	Decision: Approved.	
88.	Name and address of manufacturer / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Diary No. Date of R& I & fee	Form-5 Dy.No 32456 dated 28-09-2018 Rs.20,000/-28-09-2018
	Brand Name +Dosage Form + Strength	Hi-Doxy-50 Oral Powder
	Composition	Each 100 gm Contains: Doxycycline Hyclate…50gm
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	100gm,500gm, 1000gm
	Me-too status	049736 DOXYCYCLIN 500 WATER SOLUBLE POWDER.
	GMP status	26-10-2018. The firm is not found working as required under the law/rule.
	Remarks of the Evaluator.	
	Decision of 293rd : Deferred for updated GMP status of the firm from QA&LT Division. **Evaluation by PEC**(VI)**:**The firm has submitted panel inspection report dated 25-11-2019, the panel recommended renewal of DML.	
	Decision: Approved with innovator's specification.	
89.	Name and address of manufacturer / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Diary No. Date of R& I & fee	Form-5 Dy.No 32457 dated 28-09-2018 Rs.20,000/- 28-09-2018
	Brand Name +Dosage Form + Strength	Biotak Oral Paste
	Composition	Each ml of Paste Contains: Abamectin…4mg Praziquantel…50mg
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	5ml, 10ml, 20ml, 30ml, 50ml, 100ml
	Me-too status	034518 EQUITAK ORAL PASTE.
	GMP status	26-10-2018. The firm is not found working as required under the law/rule
	Remarks of the Evaluator.	
	Decision: Deferred for updated GMP status of the firm from QA&LT Division. **Evaluation by PEC**(VI)**:**The firm has submitted panel inspection report dated 25-11-2019, the panel recommended renewal of DML.	

	Decision: Deferred for confirmation of required manufacturing facility for applied dosage form.	
90.	Name and address of manufacturer / Applicant	"M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21046 dated 21-06-2018 Rs.20,000/- 11-06-2018
	Brand Name +Dosage Form + Strength	Artidoxin 100/25/500 mg Tablet
	Composition	"Each Combokit Contains: **Sulfadoxine+Pyremethamine Tablets:** Each Uncoated Tablet Contains: Sulfadoxine…500mg Pyremethamine…25mg **Artesunate Tablets** Each Uncoated Tablet Contains: Artesunate…100mg"
	Pharmacological Group	Antimalarial.
	Type of Form	Form 5
	Finished product Specification	Sulfadoxine+Pyremethamine (USP), Artesunate (IP)
	Pack size & Demanded Price	1x9's, (3+6). As per SRO.
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified Drug. Manufacturer of Prequalified Product: Guilin Pharmaceutical Co. Ltd.Oral Solid Dosage workshop (OSD-1),No. 43 Qilidian Road, Guilin, Guangxi, China, 541004
	Me-too status	045098 Artesul Tablets for Adults M/s Zafa Pharmaceutical, Karachi
	GMP status	18-01-2018. Conclusion: "As per observations made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall CGMP compliance status of the firm, the panel unanimously recommend the renewal of DML no. 000610 by way of formulation granted to M/s Wnsfield Pharma Hattar."
	Remarks of the Evaluator.	
	Decision of 291st : The Registration Board deferred for submission of evidence of availability of co-blister machine. **Evaluation by PEC**(VI)**:** The firm has submitted a letter written by FID Peshawar to DDG Peshawar dated 3-4-2015 confirming the co-blister machine.	
	Decision: Deferred for confirmation of co-blister machine from inspection report.	
91.	Name and address of manufacturer / Applicant	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore
	Diary No. Date of R& I & fee	Dy.No 3985 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Brand Name +Dosage Form + Strength	Novofen Suspension 100mg/5ml
	Composition	Each 5ml contains: Ibuprofen……100mg"
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs 30.00/pack of 60ml, Rs 55.00/pack of 120ml,
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	062324 "Pironec Suspension "Atlantic Pharmaceutical (Pvt) Ltd,89-D, Industrial Eastate, Hayatabad,Peshawar.(contract manufacturing from M/s Polyfine Chempharma, Peshawar)"
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.

	Remarks of the Evaluator.	The manufacturing outline of applied formulation has not been provided. Firm has liquid syrup, Capsule and Tablet section.
	Decision of 295th : Deferred for submission of manufacturing outline for applied formulation. **Evaluation by PEC**(VI)**:** The firm has submitted the manufacturing outline.	
	Decision: Approved	
92.	**Deleted due to duplication with Sr no 91.**	
93.	Name and address of manufacturer / Applicant	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore
	Diary No. Date of R& I & fee	Dy.No 3966 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Brand Name +Dosage Form + Strength	Thiosid Capsules 8mg
	Composition	Each Capsule Contains: Thiocolchicoside…8mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished product Specification	Mfg
	Pack size & Demanded Price	Rs. 525/pack 2x10"s Capsule.
	Approval status of product in Reference Regulatory Authorities.	MuscoRil 4 mg capsule rigide MuscoRil 8 mg capsule rigide AIFA Approved
	Me-too status	069906 "Caelyx Capsules M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator.	The manufacturing outline of applied formulation has not been provided. □ European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. □ Medicine only to be used at low doses for additional short-term relief of painful muscle contractures
	Decision of 295th : Deferred for submission of manufacturing outline for applied formulation. **Evaluation by PEC**(VI)**:** The firm has submitted the manufacturing outline.	
	Decision: Approved with innovator's specification.	
94.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Depin Tablet 12.5mg
	Composition	Each enteric film coated controlled release tablet contains: Paroxetine as HCl…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 8758 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	10"s,14"s,30"s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved.
	Me-too status	Panox CR Tablet 12.5 mg Reg. No. 081953 of M/s Regal Pharmaceuticals,Islamabad
	GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance.
	Previous decision	**Deferred in 295th meeting** for revision of formulation as per innovator / reference product along with submission of requisite fee.
	Evaluation by PEC(VI)	The firm has initially applied for "each enteric coated tablet contains: Paroxetine as HCl 12.5mg, later the firm has revised its

		formulation as per the reference product and submitted PKR 5,000/- fee. Dated 31-8-2020 Deposit Slip No0814923
	Decision: Deferred for submission of differential fee of Rs. 15000/-.	
95.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd.Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Depin Tablet 25mg
	Composition	Each enteric film coated controlled release tablet contains: Paroxetine as HCl…25mg
	Diary No. Date of R& I & fee	Dy.No 8759 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	10"s,14"s,30"s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved.
	Me-too status	Panox CR Tablet 25 mg Reg. No. 081954 of M/s Regal Pharmaceuticals, Islamabad
	GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance.
	Previous decision	**Deferred in 295th meeting** for revision of formulation as per the innovator / reference product along with submission of requisite fee.
	Evaluation by PEC(VI)	The firm has initially applied for "each enteric coated tablet contains: Paroxetine as HCl 25mg, later the firm has revised its formulation as per the reference product and submitted PKR 5,000/- fee. Dated 31-8-2020 Deposit Slip No0814922
	Decision: Deferred for submission of differential fee of Rs. 15000/-.	
96.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd.Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Depin Tablet 37.5mg
	Composition	Each enteric film coated controlled release tablet contains: Paroxetine as HCl…37.5mg
	Diary No. Date of R& I & fee	Dy.No 8760 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	10"s,14"s,30"s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved.
	Me-too status	Deroxat CR 37.5mg Tablet Reg. No. 069948 of M/s Global Pharmaceuticals, Islamabad
	GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance.
	Previous decision	**Deferred in 295th meeting** for revision of formulation as per innovator/reference product alongwith submission of requisite fee.
	Evaluation by PEC(VI)	The firm has initially applied for "each enteric coated tablet contains: Paroxetine as HCl 37.5mg, later the firm has revised its formulation as per the reference product and submitted PKR 5,000/- fee. Dated 31-8-2020 Deposit Slip No0814924
	Decision: Deferred for submission of differential fee of Rs. 15000/-.	
97.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Dopicard Injection 200mg/5ml
	Composition	Each 5ml ampoule contains: Dopamine HCl…200mg

	Diary No. Date of R& I & fee	Dy.No 8775 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Monoamine oxidase B inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1‟s,10‟s,50‟s,100‟s, 5ml glass ampoules
	Approval status of product in Reference Regulatory Authorities.	Dopamine Hydrochloride 40mg/ml Concentrate for Solution for Infusion by M/s Mercury Pharma International Ltd (MHRA) Approved
	Me-too status	Dopamine 200mg Injection Reg. No. 005935 of M/s LC & PW
	GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance.
	Previous decision	**Deferred in 295th meeting for** □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC(VI)	The firm has initially applied for “each 5ml ampoule contains: Dopamine HCl…40mg, later the firm has submitted revised Form-5 as per the reference product i.e each 5ml ampoule contains: Dopamine HCl…200mg and submitted PKR 20,000/- fee. Dated 31-8-2020 Deposit Slip No0814925
	Decision: Approved	
98.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	AVN-Plus 10/10mg Tablet
	Composition	"Each delayed release film coated tablet contains: Doxylamine Succinate…10mg Pyridoxine HCL…10mg"
	Diary No. Date of R& I & fee	Dy.No 40343 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antihistamines for Systemic Use, Vitamin
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x30, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Xonvea 10 mg/10 mg gastro-resistant (film coated) MHRA Approved.
	Me-too status	75838 Brand Name: Vomipreg Tablet Manufacturer Name : Nexus Pharma,
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Previous Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by Registration Board in 275th meeting. Firms Response Firm has revised their formulation from immediate release to delayed release tablet with submission of Rs, 5000/-. Shortcoming • The form 5 refers to Annexure A to D but the relevant data has not been submitted. Firms Response Annexure A to D has not been provided by the firm.
	Previous decision (M-295)	Deferred for submission of application with all its annexure.
	Firm’s response(VI)	Firm has submitted relevant data for the annexures of Form 5 including master formulation and manufacturing method.
	Decision: Approved with innovator’s specification.	

99.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Ketero 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40344 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Acetic acid derivatives and related substances,NSAID M01AB15
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Toradol oral tablets (ketorolac tromethamine tablets) USFDA Approved.
	Me-too status	060804 Brand Name: Kelac Manufacturer Name: Rotex Pharma (Pvt.) Ltd. (Formerly Rotex Medica)
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Previous Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5.
	Previous decision (M-295)	Deferred for submission of signed application on Form 5.
	Firm's response(VI)	Firm has submitted signed copy of Form 5.
	Decision: Approved.	
100	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Coblmn 500mcg Tablet
	Composition	"Each sugar coated tablet contains: Mecobalamin…500mcg"
	Diary No. Date of R& I & fee	Dy.No 40341 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Vitamin B12.
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	30's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved sugar coated
	Me-too status	081876; Brand Name: Heam 500 mcg Tablet Manufacturer Name: Linear Parma,
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Previous Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5. • The applied formulation is sugar coated tablet whereas, master formulation and manufacturing method is of film coated tablet.
	Previous decision (M-295)	Deferred for the following: •Submit master formulation & manufacturing method of relevant formulation which is mecobalamin 500mcg sugar coated tablet. •Submit signed application on Form 5.
	Firm's response(VI)	Firm has submitted signed copy of Form 5 along with master formulation and manufacturing method for sugar coated tablets.
	Decision: Approved	
101.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Enox Tablet 400mcg
	Composition	"Each Film Coated Tablet Contains: Enoxacin Sesquihydrate…400mg"
	Diary No. Date of R& I & fee	Dy.No 40334 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Fluoroquinolones J01MA04

	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA.
	Me-too status	010174; Enoxabid 400mg Tab M/s Abbott
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Previous Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5.
	Previous decision (M-295)	Deferred for the following submission of signed application of applied formulation on Form 5.
	Firm's response(VI)	Firm has submitted signed copy of Form 5.
	Decision: Deferred for the confirmation of product discontinuation reasons in USFDA.	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

Extension in implementation timelines of SRO 713(I)/2018

The Authority in its 72nd meeting discussed regarding the "Extension in implementation timelines of SRO 713(I)/2018 and decided as follows:-

1. Allowed those companies, for which panel for inspection has been constituted before 07-03-2019, to submit registration applications on Form 5 instead of Form 5F for initial 10 molecules per section only.
2. The exemption will remain valid till 31-12-2019.
3. No further exemption will be granted in any case.
4. Inspectors / panel members are advised to formally report every visit. Concerned Division were advised to specify a timelines for conducting/ concluding panel inspection.

Name of Firm	Date of issuance of panel inspection letter	Date of issuance of DML	Date of Submission of applications	Consideration of application in Registration Board
M/s KBR Pharmaceuticals, Hattar	8th March 2018	28th June 2019	November 2019	

The submission of following applications on foirm-5 are in line with the decision of Authority

M/s. KBR Pharmaceuticals, Plot # 123 - B, Phase V, Industrial Estate, Hattar.
Cream & Ointment Section (General) 16 products/ 7 molecules

102.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rizonal Lotion 2 % w/w
	Diary No. Date of R& I & fee	Diary No: 23226 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each gm Contains: Ketoconazole…20mg (2% w/w)
	Pharmacological Group	Antifungals for topical use
	Type of Form	Form-5
	Finished Product Specification	BP Specs
	Pack size & Demanded Price	60 mL & 100 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dandrazol 2 % W/W Topical Solution Transdermal Limited, Merlin House, Brunel Road, Theale, Reading,RG 7 4 AB **(MHRA)**
	Me-too status	Ketocal Lotion by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	
103.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rizonal Cream 2 % w/w
	Diary No. Date of R& I & fee	Diary No: 23225 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Ketoconazole…20mg (2% w/w)
	Pharmacological Group	Antifungals for topical use

	Type of Form	Form-5
	Finished Product Specification	BP Specs
	Pack size & Demanded Price	5 g , 10 g& 15 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ketoconazole Cream 2% by Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1
	Me-too status	Ketocon Cream by M/s Valour Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved	
104.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rezemus Ointment 0.1 % w/w
	Diary No. Date of R& I & fee	Diary No: 23228 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Tacrolimus (as monohydrate)…… 1 mg (0.1 %w/w)
	Pharmacological Group	Macrolide Calcineurin Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs
	Pack size & Demanded Price	10 g& 30 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTOPIC (tacrolimus) Ointment 0.1%w/w M/s LEO PHARMA AS (USFDA Approved)
	Me-too status	Crolimus Cream by M/s Valor Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved with innovator's specification.	
105.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rezemus Ointment 0.03 % w/w
	Diary No. Date of R& I & fee	Diary No: 23227 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram of Ointment Contains: Tacrolimus (as monohydrate)…… 0.3 mg (0.03 %w/w)
	Pharmacological Group	Macrolide Calcineurin Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs
	Pack size & Demanded Price	10 g& 30 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTOPIC (tacrolimus) Ointment 0.03%w/w M/s LEO PHARMA AS (USFDA Approved)
	Me-too status	Crolimus Cream by M/s Valor Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved with innovator's specification	
106.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rinoxin Lotion 2 % w/v
	Diary No. Date of R& I & fee	Diary No: 23229 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each mL Contains: Minoxidil……..20 mg (2%w/v)
	Pharmacological Group	Other dermatologicals
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	60 mL & 90 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Regaine for men extra strength topical solution by McNeil (**MHRA** Approved)
	Me-too status	Minoxical Lotion by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)

	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	
107.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rinoxin Lotion 5 % w/v
	Diary No. Date of R& I & fee	Diary No: 23230 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each mL of Lotion Contains: Minoxidil……..50 mg (5%w/v)
	Pharmacological Group	Other dermatologicals
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	60 mL & 90 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Regaine for men extra strength topical solution by McNeil (**MHRA** Approved)
	Me-too status	Minoxical Lotion by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	
108.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Removate Ointment 0.05 % w/w
	Diary No. Date of R& I & fee	Diary No: 23231 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Clobetasol Propionate……0.5mg (0.0.5%w/w)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	5 g, 10 g, 15 g & 25 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Impoyz 0.05%w/w OINTMENT Manufactured for Promius Pharma LLC., by DPT Laboratories Inc., San Antonio, TX 7821
	Me-too status	Clobetacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved	
109.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Removate Cream 0.05 % w/w
	Diary No. Date of R& I & fee	Diary No: 23232 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Clobetasol Propionate……0.5mg (0.0.5%w/w)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	5 g, 10 g, 15 g & 25 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Clobetacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved	
110.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Removate Lotion 0.05 % w/v
	Diary No. Date of R& I & fee	Diary No: 23233 , 08-11-2019 , Rs: 20,000/- , 06-11-2019

	Composition	Each Gram Contains: Clobetasol Propionate……0.5mg (0.05%w/v)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	20 mL & 30 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Impoyz 0.05%w/v Manufactured for Promius Pharma LLC., by DPT Laboratories Inc., San Antonio, TX 7821
	Me-too status	Clobetacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	
111.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ransomet Cream 0.1 % w/w
	Diary No. Date of R& I & fee	Diary No: 23234 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Mometasone Furoate……..1mg (0.1%w/w)
	Pharmacological Group	Corticosteroid, potent group III
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	5 g, 10 g, 15 g & 30 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mometacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	Segregated dispensing booth for steroid products are not confirmed
	Decision: Deferred for the confirmation of segregated booth for steroid products as per decision of CLB.	
112.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ransomet Ointment 0.1 % w/w
	Diary No. Date of R& I & fee	Diary No: 23235 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each Gram Contains: Mometasone Furoate……..1mg (0.1%w/w)
	Pharmacological Group	Corticosteroid, potent group III
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	5 g, 10 g, 15 g & 30 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Momate by M/s Maxitech Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	Segregated dispensing booth for steroid products are not confirmed
	Decision: Deferred for the confirmation of segregated booth for steroid products as per decision of CLB.	
113.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ransomet Lotion 0.1 % w/v
	Diary No. Date of R& I & fee	Diary No: 23236, 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each mL Contains: Mometasone Furoate……..1mg (0.1%w/v)
	Pharmacological Group	Corticosteroid, potent group III
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	20 mL & 30 mL / As per SRO

	Approval status of product in Reference Regulatory Authorities.	Elocon 0.1% w/w scalp lotion by Merck (**MHRA** Approved)
	Me-too status	Mometacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	Segregated dispensing booth for steroid products are not confirmed
	Decision: Deferred for the confirmation of segregated booth for steroidal products as per decision of CLB and manufacturing facility i.e. Lotion section	
114.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rotrin Lotion 5 % w/v
	Diary No. Date of R& I & fee	Diary No: 23237 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each mL Contains: Permethrin……..50 mg (5%w/v)
	Pharmacological Group	Anti infective
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs
	Pack size & Demanded Price	30 mL & 60 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Permethrin 5 % w/v Lotion M/s GSK **(MHRA Approved)**
	Me-too status	Pestlin by M/s Atco Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	
115.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rotrin Cream 5 % w/v
	Diary No. Date of R& I & fee	Diary No: 23238 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each gram contains: Permethrin……..50 mg (5%w/w)
	Pharmacological Group	Anti infective
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs
	Pack size & Demanded Price	10 g & 30 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	LYCLEAR Dermal Cream 5 % w/w Omega Pharma ,UK **(MHRA Approved)**
	Me-too status	Nixcal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved with innovator's specification.	
116.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ralagin V Lotion 1 % w/v
	Diary No. Date of R& I & fee	Diary No: 23239 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each mL Contains: Clindamycin (as Phosphate)……..10 mg (1% w/v)
	Pharmacological Group	Lincomycin Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	30 mL & 60 mL / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cleocin T 1% Lotion by M/s Pfizer MHRA Approved
	Me-too status	Acsolve Lotion by M/s Atco Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Deferred for the confirmation of manufacturing facility i.e. Lotion section	

117.	Name and address of manufacturer / Applicant	M/s KBR Pharmaceuticals, 123 - B, Phase V, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ralagin V Cream 2 % w/w
	Diary No. Date of R& I & fee	Diary No: 23240 , 08-11-2019 , Rs: 20,000/- , 06-11-2019
	Composition	Each gram Contains: Clindamycin (as Phosphate)……..20 mg (2% w/w)
	Pharmacological Group	Lincomycin Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	10 g, 20 g & 40 g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dalacin 2% Cream (MHRA Approved)
	Me-too status	Clindacal by M/s Caliph Pharma
	GMP status	New License (DML # 000906 Dated 28-06-2019)
	Remarks of the Evaluator. (VI)	
	Decision: Approved.	

a. Deferred cases of New/Additional section(s)

118.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Jolip 10mg Tablet
	Composition	Each film coated Tablet Contains: Zolpidem as tartrate…10mg
	Diary No. Date of R& I & fee	Dy.No 16246 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Pharmacological Group	Sedative agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14'S /As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olida 10mg Tablets of M/s Glitz Pharmaceuticals (Reg.# 081418)
	GMP status	New Section
	Remarks of the Evaluator. (VI)	The firm has initially applied the product as uncoated tablet , now they revised it in film coated as per reference product along with the submission of fee Rs. 5,000 dated 2-9-2020 Deposit Slip No. 2049329 Central Licensing Board in its 270th meeting held on 23rd MAY, 2019 has considered and approved the following 2 additional section of firm M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan as under:- Sr. No Section 01 Tablet Section (Psychotropic/Narcotic) 02 Oral Liquid/Suspension General Section
	Previous Decision	Decision of 291st : Deferred for consideration on its turn with respect to the queue.
	Evaluation by PEC: (VI) The firm has submitted that the above product is psychotropic. The same has been confirmed from green list of INCB and also from controlled division.	
	Decision: Approved.	

Case no. 06 Registration applications of import cases

a. New Cases (Human)

b. New Cases (Veterinary)

c. Deferred cases

i. Human

119.	Name and address of Applicant	M/s OBS Pakistan (Pvt.) Limited , C-14, Manghopir Road, S.I.T.E Karachi
	Detail of Drug Sale License	**Address**: C-14, Manghopir Road, S.I.T.E Karachi **Validity:** 23 May 2018 **Status:** Drug License by Way of Retail sale
	Name and address of manufacturer	M/s Santen Pharmaceutical Co. Ltd Shiga Plant 348-3, Aza-suwa, Oaza- shide, Taga-cho, Inukami-gun, Shiga, Japan M/s Santen Pharmaceutical Co. Ltd Shiga Plant will be responsible for • Preparation of drug solution process. • Filtration for sterilization and filling process. • Release testing of product. and M/s Santen Pharmaceutical Co. Ltd Noto Plant 2-14, Sikinami will be responsible for • Packaging and labeling process. • Release testing of product • Batch release.
	Name and address of marketing authorization holder	M/s Santen Pharmaceutical Co. Ltd Shiga Plant 348-3, Aza-suwa, Oaza- shide, Taga-cho, Inukami-gun, Shiga, Japan
	Name of exporting country	Japan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.3466 Dated 26-01-2018
	Fee including differential fee	Rs. 100,000/- Dated 26-01-2018
	Brand Name +Dosage Form + Strength	Taflotan Opthalmic Solution 0.0015%w/v
	Composition	Each ml contains: Tafluprost….15ug
	Finished Product Specification	Inhouse
	Pharmacological Group	Glaucoma and Ocular Hypertension
	Shelf life	3 years
	Demanded Price	MRP as per Originator pack
	Pack size	1's 2.5ml polypropylene bottle with polypropylene dropper
	International availability	Approved in USFDA Zioptan By Merck Sharp, USA
	Me-too status	N/A
	Detail of certificates attached	**Original legalized CoPP** Certificate No: 5141 Certifying Authority: Ministry of Health, Labour and Welfare, Government of Japan Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 6-02-2017 **GMP certificate** Certificate No: 4874 Certifying Authority: Ministry of Health, Labour and Welfare Issue date: 27-01-2017 **Free sale Certificate** Certificate No: 4351 Certifying Authority: Ministry of Health, Labour and Welfare Issue Date**:**22-11-2017 **Letter of Authorization** Date of Agreement:05-10-2017 Validity :3 Years

	Remarks of the Evaluator.	**Firm provided the stability data at following conditions;** ● Long term test: 25C/40%RH & 30/75%RH (36 months) ● Accelerated Test: 40C/NMT 25%RH The submitted stability data for accelerated condition is not as per Zone IV A requirement. **Firm submitted the following reply;** The stability testing was conducted in compliance with Stability testing of New Drug Substances and Products. The accelerated test conditions has been performed under low humidity conditions 40C/25%RH instead of climate zone IVA high humidity condition which is not recommended and preferred for semi permeable container as stated in ICH. *A Significant change has been observed in assay value of Tafluprost for all the three batches MTD1332, MTD1333 and MTD1334 at long term stability condition. Clarify.* Upto 36 months storage at 30C/75% the decrease of tafluprost content is observed (6.5%-6.7%). The increase of the related substances as degradation product of tafluprost are observed (1.6%-1.8%), but it is no problem for safety. According to the above result , the amount of total degradation products is less then the decrease of tafluprost content, it is considered that the reason for the decrease of tafluprost are not only degradation but also adsorption to container. The results of the other tests items are within the specifications, and there are no significant changes. The stability is affected by temperature but it is stable for 36 months after distribution under light protected and below 30C.
	Previous Decision(M-282): Deferred for the following reasons: ● Submission of long term stability data according to Zone IVA condition. Submitted data for long term stability is at 25C/40%RH which is not according to Zone IVA for semi-permeable containers. ● Submission of test for determination of potential water loss in case of semipermeable membrane.	
	Evaluation by PEC: Firm submitted the following reply: ● Submission of long term stability data according to Zone IVA condition. Submitted data for long term stability is at 25°C/40%RH which is not according to Zone IVA for semi- permeable containers. Please note that the stability conducted on 25°C±2/40%±5 complies the criteria of WHO guidelines which clearly states the condition in which whether the long term studies are performed at on 25°C±2/40%±5 or 30°C±2/35%±5 is determined by the climatic condition under which the FPP is intended to be marketed. . Testing at 30 °C/35% RH can be an alternative to the storage condition at 25 °C/40% RH. Also the region has claimed that incase of semi-permeable container, the low humidity condition 25°C±2/40%RH±5 is a more severe storage condition than high humidity condition 30 °C/35% RH. **Evaluation** However, the data is at 25 °C/40% RH and not at 30 °C/35% RH. Therefore, the stability is not as per guideline. Moreover, the low humidity condition is 30 °C/35% RH and not 25°C/40%RH. The firm has performed stability testing according to ASEAN requirement i.e. at 30°C/75%RH but test for water loss has not been conducted. Moreover, the stability data is of Shiga Plant whereas, M/s Santen Pharmaceutical Co. Ltd Noto Plant 2-14, Sikinami will be responsible for i. Packaging and labelling process. ii. Release testing of product iii. Batch release.	
	Decision of 288th : Deferred for the following reasons: ● Submission of long term stability data from M/s Santen Pharmaceutical Co. Ltd Noto Plant 2-14, Sikinami according to Zone IVA condition. Submitted data for long term stability is at 25C/40%RH which is not according to Zone IVA for semi-permeable containers. ● Submission of test for determination of potential water loss in case of semi-permeable membrane.	

	Evaluation by PEC(VI)**:** ● The firm submitted the reply that they calculated stability data at 30ºC/35% RH and water loss calculation for all the stability conditions in accordance with stability guidelines "Stability testing of New Drug Substances and Products" ICH {ICH Q1A (R2). According to these guidelines an alternative approach is recommended for studies at the low relative humidity that is to perform the stability studies under higher relative humidity and deriving the water loss at the low relative humidity through calculations. ● Firm proposed following solution for this: The firm has proposed that the results derived from calculated data for 30ºC and 35% RH has shown no significant change in product specifications there was insignificant water loss to alter the product specifications proven by results.
	Decision: Deferred for further evaluation in accordance with the ICH stability studies guidelines

Case no. 07 Registration applications of drugs for which stability study data is submitted

a. New cases
b. Deferred cases
c. Verification of stability study data
d. Exemption from onsite verification of stability data

120.	Name and address of manufacturer/ Applicant	M/s. Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name +Dosage Form+ Strength	Ertugli 15mg tablets
	Composition	Each film coated tablets contains: Ertugliflozin as L-Pyroglutamic acid…….15mg
	Diary No. Date of R&I & fee	14th December, 2018, Rs. 50,000/-
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturers Specification
	Pack size & Demanded Price	**Pack Size:** 7s, 10s, 14s, 20s, 28s & 30s MRP: Rs. 4200/- per 7s, Rs. 6000/- per 10s, Rs. 8400/- per 14s, Rs. 12000/- per 20s, Rs. 16800/- per 28s, Rs. 18000/- per 30s.
	Approval status of product in	STEGLATRO TABLET 15mg
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	Ertugli 15mg tablets		
Name ofManufacturer	M/s. Atco Laboratories (Pvt). Limited, B-18, S.I.T.E., Karachi.		
ManufacturerofAPI	**Ertugliflozin as L-Pyroglutamic acid**: Zhejiang Hongyuan Pharmaceutical Co, Ltd.China		
API Lot No.	**Ertugliflozin as L-Pyroglutamic acid**: ET20180523		
Description of Pack (Container closure system)	Alu-Alu blisters 1 x 10's tablets		
StabilityStorage Condition	Accelerated: 40°C and 75% RH Real Time: 30°C and 75% RH		
Time Period	Accelerated: 6months Real Time: 12months		
Frequency	Accelerated: 0, 1, 3, 6 months Real Time: 0, 3, 6,9,12 months		
Batch No.	216 G 18	217 G 18	218 G 18
Batch Size	6000 Tablets	6000 Tablets	6000 Tablets

ManufacturingDate	01-08-2018	01-08-2018	01-08-2018
Date ofInitiation	25-08-2018	25-08-2018	25-08-2018
No. of Batches	03		
Date of Submission	10-02-2020		

DOCUMENTS IDATAPROVIDED BYTHEAPPLICANT

Sr. No.	Documents ToBeProvided	Status
1.	COA of API.	**Ertugliflozin as L-Pyroglutamic acid**: Copy of COA (Batch # ET20180523) from M/s Zhejiang Hongyuan Pharmaceutical Co, Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Ertugliflozin as L-Pyroglutamic acid**: Copy of GMP certificate (certificate # ZJ20180032) issued by China Food and Drug administration is submitted. It is valid till 14-03-2023.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Ertugliflozin as L-Pyroglutamic acid**: The firm has submitted copy of commercial invoice for the purchase of Ertugliflozin as L-Pyroglutamic acid attested by DRAP, Karachi dated 13-06-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continuerealtime stability studytillassigned shelflifeof the product.	Yes
8.	Commitment to follow DrugSpecification Rules,1978.	Yes

REMARKS OF EVALUATOR

REQUEST OFEXEMPTIONFROMONSITEINSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

AdministrativePortion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last three years.	Firm has referred to onsite inspection report of their product "Rofl 500mcg tablet", which was presented in 277th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Atco Laboratories Limited, Karachi.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin as L-Pyroglutamic acid: The firm has submitted copy of commercial invoice for the purchase ofErtugliflozin as L-Pyroglutamic acid attested by DRAP, Karachi dated13-06-2018.
3.	Documents for the procurement of reference standard and impuritystandards.	The firm has submitted fffffcopy of COA of the following: Ertugliflozin as L-Pyroglutamic acid Working Standard.

<table>
<tr><td>4.</td><td>Approval of API/DML/GMP certificate of API manufacturer issued by regulatory authority of country of</td><td>Ertugliflozin as L-Pyroglutamic acid: Copy of GMP certificate (certificate # ZJ20180032) issued by China Food and Drug administration is submitted. It is valid until 14-03-2023.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for evaluation of vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Ertugliflozin as L-Pyroglutamic acid: Copy of COA (Batch#ET20180402WS) from M/s. Zhejiang Hongyuan Pharmaceutical Co. Ltd, China is submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurementof excipients used in product development?</td><td>The firm has submitted photocopy of invoices/COAs of the excipient used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>Listof qualified staff involved in product development with relevant</td><td>The firm has submitted List of Qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Protocols for the development of new product.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>216G18</td><td>6000 Tablets</td><td>01-08-2018</td></tr>
<tr><td>217G18</td><td>6000 Tablets</td><td>01-08-2018</td></tr>
<tr><td>218G18</td><td>6000 Tablets</td><td>01-08-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No.</th><th>Total No. of Tablets for Stability Testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>216G18</td><td>550</td><td>210</td><td>340</td></tr>
<tr><td>217G18</td><td>550</td><td>210</td><td>340</td></tr>
<tr><td>218G18</td><td>550</td><td>210</td><td>340</td></tr>
</table></td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from Aug-2018 to Aug-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw material specifications, raw material testing procedures along with COA for Ertugliflozin L Pyroglutamic Acid.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ertugli 15mg Tablets” along with stability Study reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches from M/s. Zhejiang Hongyuan Pharmaceutical Co. Ltd, China according to zone IV A conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has used the excipients of innovator.</td></tr>
</table>

18.	Record of comparative dissolution data.	Firm has provided justification that the formulation of our product Ertugli Tablets Range is based on the formulation of Innovator product. According to EMA Assessment Report EMEA/H/C/004315/0000, the replacement of dissolution testing by disintegration testing at release and stability is acceptable, as Ertugliflozin is highly soluble and highly permeable and classified as BCS class 1 molecule. Hence, on the basis of dissolution data, the comparative studies may be waived and there is no need to calculate similarity factor and product is stable and comparable.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The Firm has submitted audit trail reports for complete stability studies analysis of three batches at each time point.

Remarks of the Evaluator (VI)**:**

The firm did not conduct dissolution studies. The firm submitted that our product is based on EMA assessment report of innovator product which states that" The replacement of dissolution testing by disintegration testing at release and stability is acceptable" So there is no need to perform dissolution test.

The firm has not performed content uniformity test during stability studies and submitted that as per WHO stability testing Annex-10, Stability studies are performed on critical quality attributes and there is no need to perform content uniformity test during stability studies.

Decision: Deferred for scientific justification for not perfoming dissolution studies since innovator has performed dissolution test with limits of NLT Q in 15min.

121.	Name and address of manufacturer / Applicant	M/s. Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Ertugli 5mg tablets
	Composition	Each film coated tablets contains: Ertugliflozin as L-Pyroglutamic acid…….5mg
	Diary No. Date of R& I & fee	Rs. 50,000/- R&I 14th December, 2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturers Specification
	Pack size & Demanded Price	Pack Size: 7s, 10s, 14s, 20s, 28s & 30s MRP: Rs. 1400/- per 7s, Rs. 2000/- per 10s, Rs. 2800/- per 14s, Rs. 4000/- per 20s, Rs. 5600/- per 28s, Rs. 6000/- per 30s
	Approval status of product in Reference Regulator Authorities	STEGLATRO TABLET 5mg MERCK SHARP AND DOHMECORP, USA
	GMP status	
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Ertugli 5mg tablets
Name of Manufacturer	M/s. Atco Laboratories (Pvt). Limited, B-18, S.I.T.E., Karachi.
Manufacturer of API	**Ertugliflozin as L-Pyroglutamic acid**: Zhejiang Hongyuan Pharmaceutical Co, Ltd.
API Lot No.	**Ertugliflozin as L-Pyroglutamic acid**: ET20180523
Description of Pack (Container closure system)	Alu-Alu blisters 1 x 10's tablets
Stability Storage Condition	Accelerated: 40°C and 75% RH Real Time: 30°C and 75% RH
Time Period	Accelerated: 6months Real Time: 12months

Frequency	Accelerated: 0, 1, 3, 6 months Real Time: 0, 3, 6,9,12 months		
Batch No.	219 G 18	220 G 18	221 G 18
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	01-08-2018	01-08-2018	01-08-2018
Date of Initiation	29-08-2018	29-08-2018	29-08-2018
No. of Batches	03		
Date of Submission	10-02-2020		

DOCUMENTS I DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**Ertugliflozin as L-Pyroglutamic acid**: Copy of COA (Batch # ET20180523) from M/s Zhejiang Hongyuan Pharmaceutical Co, Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Ertugliflozin as L-Pyroglutamic acid**: Copy of GMP certificate (certificate # ZJ20180032) issued by China Food and Drug administration is submitted. It is valid till 14-03-2023.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Ertugliflozin as L-Pyroglutamic acid**: The firm has submitted copy of commercial invoice for the purchase of Ertugliflozin as L-Pyroglutamic acid attested by DRAP, Karachi dated 13-06-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data l documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR(VI)

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Rofl 500mcg tablet", which was presented in 277th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Atco Laboratories Limited, Karachi.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin as L-Pyroglutamic acid**: The firm has submitted copy of commercial invoice for the purchase of Ertugliflozin as L-Pyroglutamic acid attested by DRAP, Karachi dated13-06-2018.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of COA of the following:
Ertugliflozin as L-Pyroglutamic acid Working Standard.</td></tr>
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<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of Qualified staff involved in product development department.</td></tr>
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<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from Aug-2018 to Aug-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw material specifications, raw material testing procedures along with COA for Ertugliflozin L Pyroglutamic Acid.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ertugli 5mg Tablets” along with stability Study reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches from M/s. Zhejiang Hongyuan Pharmaceutical Co. Ltd, China according to zone IV A conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has used the excipients of innovator.</td></tr>
</table>

18.	Record of comparative dissolution data.	Firm has provided justification that the formulation of our product Ertugli Tablets Range is based on the formulation of Innovator product. According to EMA Assessment Report EMEA/H/C/004315/0000, the replacement of dissolution testing by disintegration testing at release and stability is acceptable, as Ertugliflozin is highly soluble and highly permeable and classified as BCS class 1 molecule. Hence, on the basis of dissolution data, the comparative studies may be waived and there is no need to calculate similarity factor and product is stable and comparable.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The Firm has submitted audit trail reports for complete stability studies analysis of three batches at each time point

Remarks of the Evaluator (VI)**:**

The firm did not conduct dissolution studies. The firm submitted that our product is based on EMA assessment report of innovator product which states that" The replacement of dissolution testing by disintegration testing at release and stability is acceptable" So there is no need to perform dissolution test.

The firm has not performed content uniformity test during stability studies and submitted that as per WHO stability testing Annex-10, Stability studies are performed on critical quality attributes and there is no need to perform content uniformity test during stability studies on the applied product.

Decision: Deferred for scientific justification for not perfoming dissolution studies since innovator has performed dissolution test with limits of NLT Q in 15min.

Sr. No.	Name and address of manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
122.	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi	GLARDIN-M Tablets 12.5mg + 850mg Each film coated tablet contains: Empagliflozin……12.5mg Metformin HCl …….850mg Anti-diabetic Manufacturer Specs.	Form 5D PKR 50,000/- 25-03-2016 14's : Rs. 4300/-	SYNJARDY Tablets 12.5mg + 850mg by Boehringer Ingelheim Ltd, UK (**MHRA** Approved) Last GMP Inspection dated 16-12-2019 concluding acceptable level of GMP compliance status
	Remarks of the Evaluator:			

STABILITY STUDY DATA

Drug	GLARDIN-M Tablets 12.5mg + 850mg
Name of Manufacturer	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi
Manufacturer of API	Empagliflozin: M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China Metformin HCl: M/s Wanbury Limited India
API Lot No.	Empagliflozin: 20190322 Metformin HCl: MT18751217
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Real time: 0,3,6 (months)

	Accelerated: 0,1,2,3,4,6 (months)		
Batch No.	489DS01	489DS02	489DS03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	24.05.2019	20.06.2019	20.06.2019
Date of Initiation	28-06-2019	10-07-2019	10-07-2019
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Jiangsu Fooad and drug administration. (Certificate # JSHAHAQ2017005). The certificate is valid till 3-3-2021. Firm has submitted copy of GMP certificate of M/s Wanbury Limited India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice confirming import of 10 Kg Empagliflozin dated 05-04-2019 for Batch No. 20190322. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
Administrative Portion		
1	Reference of last onsite panel inspection for instant dosage form conducted during last two years	Firm has referred to onsite inspection report of their product for Arcox (Etoricoxib) Tablets 90mg & 120mg on 17th September, 2018 and was presented in 286th Drug Registration Board meeting held on 14th – 16th November, 2018. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.

2	Documents for the procurement of API with approval from DRAP (in case of import)	Firm has submitted ADC attested invoice confirming import of 10 Kg Empagliflozin dated 05-04-2019 for Batch No. 20190322. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
3	Documents for the procurement of reference standard and impurity standards	Firm has submitted COA and invoice of reference standard and impurity standards.
4	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China (Certificate # JS20160548) issued by Jiangsu Food and Drug Administration. The certificate is valid till 3-3-2021 Firm has submitted copy of GMP certificate of M/s Wanbury Limited India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
5	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation report of Empagliflozin and Metformin HCl, filled and signed by technical persons of the firm.
6	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, reference standard and impurity standards.
7	Documents for the procurement of excipients used in product development	Firm has submitted documents for procurement of excipients used in formulation of applied product.
8	List of qualified staff involved in product development with relevant experience	Firm has provided list of qualified staff of product development section and R&D Analytical Laboratory comprising of 43 qualified staff.
Production Data		
9	Authorized Protocols/SOP for the development & stability testing of trial batches	Firm has submitted authorized stability protocols / SOP for development and stability testing of trial batches.
10	Complete batch manufacturing record of three stability batches	Firm has submitted copy of Batch Manufacturing Record for all the three stability batches.
11	Record of remaining quantities of stability batches	Firm has provided following remaining quantities for each batch: 489DS01 : 280 Tablets 489DS02 : 298 Tablets 489DS03 : 298 Tablets
QA/QC Data		
12	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing.
13	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of Empagliflozin and Metformin HCl.
14	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted copy of method of analysis of FPP and complete record of testing of stability batches along with chromatograms, lab reports, raw data sheets etc.
15	Reports of stability studies of API from manufacturer.	Firm has submitted stability studies reports of three batches of Empagliflozin and Metformin HCl.
16	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in product development.
17	Drug-excipients compatibility studies.	Firm has submitted that same excipients has been used as used by innovator 'Synjardy Tablets 12.5mg + 850mg'. However, there is only difference in the film-coating material. Therefore, Drug-excipients compatibility studies were not performed.

18	Record of comparative dissolution data.	Firm has submitted data of comparative dissolution profile (in pH 1.2 HCl, Acetate Buffer pH 4.5, Phosphate buffer pH 6.8) with the innovator brand (Synjardy Tablets).
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Decision: Registration Board decided to approve registration of GLARDIN-M Tablets 12.5mg + 850mg with Innovator's specifications by M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
123.	**M/s Genix Pharma (Pvt.) Ltd.** Karachi	GVIA-M XR Tablets Each extended-Release tablet contains: Sitagliptin Phosphate eq. to Sitagliptin ……50mg Metformin Hydrochloride …….500mg (Innovator's Specifications)	Form 5 Dy no 26428 01-08-2018, Fee: 20,000/- As per SRO 10's, 14's, 20's, 30's,	Janumet XR Tablets 50mg+500mg, M/s Merck Sharp and Dohme Firm is operating at acceptable level of GMP compliance as per inspection dated 16-02-2018	**Deferred for submission of stability data and relevant documents.** (M-286th)

STABILITY STUDY DATA

Drug	GVIA-M XR 50mg+500mg Tablets		
Name of Manufacturer	M/s Genix Pharma (Pvt.) Ltd.		
Manufacturer of API	Sitagliptin:M/s Fuxin long Rui pharmaceuticals,China Metformin: Abhilash Chemicals, India		
API Lot No.	M-20190127-D01-M06-08 & MET/B/01/19030070		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	**Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH **Real Time:** 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	**Accelerated:** 06 months **Real Time:** 06 months		
Frequency	**Accelerated:** 0, 1, 2,3,4 & 6 (Months) **Real Time:** 3,6 (Months)		
Batch No.	**19SB-121-01**	**19SB-122-02**	**19SB-123-03**
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	05-08-2019	05-08-2019	05-08-2019
No. of Batches	03		
Date of Submission	11-05-2020		

Sr. No.	Documents to Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Yes**
3.	Protocols followed for conduction of stability study and details of tests.	**Yes**
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	**Yes**
5.	Documents confirming import of API etc.	Copy of Form 7 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 16-04-2019, for the import of Sitagliptin Phosphate from the M/s Shenyang Vast Pharmatec Co Ltd, China, manufactured by Fuxin Long Rui Pharmaceutical CO.,Ltd has been submitted. Copy of Commercial Invoice (invoice no. SY190404-C) dated attested by ADC (Karachi) dated 18-04-2019 has been submitted. Copy of Form 7 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 18-03-2019, for the import of Metformin HCl from the M/s Abhilash Chemicals And Pharmaceuticals Taminadu, India has been submitted. Copy of Commercial Invoice (invoice no. GSTE-189/2018-19) dated 21-03-2019 attested by ADC (Karachi) dated 21/03/19 has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	**Yes**
7.	Commitment to continue real time stability study till assigned shelf life of the product.	**Yes**
8.	Commitment to follow Drug Specification Rules, 1978.	**Yes**

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

REMARKS OF EVALUATOR (AD PEC-I)

1. GMP of API Certificates of the concerned manufacturer is available.
2. The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter no. RA/070/20, dated 11-05-2020 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

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<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection report of their product “WYMLY Tablets 25mg (Tenofovir Alafenamide)”, which was conducted on 06-02-2018, and was presented in 281th meeting of Registration Board held on 11-13th April, 2018.
Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)”, by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks.
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i. The HPLC software is 21CFR complaint and having certificates of compliance by USFDA.
ii. Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available.
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<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Sitagliptin Phosphate:
Copy of Commercial Invoice (invoice no. SY190404-C) dated attested by ADC (Karachi) dated 18-04-2019 has been submitted.
Metformin HCl: Copy of Commercial Invoice (invoice no. GSTE-189/2018-19) dated 21-03-2019 attested by ADC (Karachi) dated 21/03/19 has been submitted.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice from M/s USP 7135 English Muffin Way Frederick, MD 21704 in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards
<table>
<tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr>
<tr><td>Sitagliptin Phosphate</td><td>1612903</td><td>200mg</td></tr>
<tr><td>Melamine</td><td>1379183</td><td>250mg</td></tr>
<tr><td>Metformin Hydrochloride</td><td>1396309</td><td>200mg</td></tr>
<tr><td>Metformin Related Compound A</td><td>1396310</td><td>30mg</td></tr>
</table></td></tr>
<tr><td>4</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Sitagliptin: M/s Fuxin Long Rui Pharmaceuticals Co Ltd, is issued written confirmation for active substance exported to EU by Liao Ning Food and Drug Administration, Peoples republic of china.\ valid upto 27th March 2021.

Metformin: M/s Abhilash Chemicals and Pharmaceuticals Pvt Ltd, 34/6A, Nayakkanpatti Village, Madurai North, Maduri District (written confirmation for active substance exported to EU issued by Ministry f health and family welfare, Central drug standard control organization)valid upto September 2021</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure”,

SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01</td></tr>
</table>

<table>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Sitagliptin Phosphate + Metformin Hydrochloride & working standards and impurity standards submitted. Detail is as under
<table>
<tr><th>Particulars</th><th>Batch no</th></tr>
<tr><td>Sitagliptin Phosphate</td><td>M-20190127-D01-M06-08</td></tr>
<tr><td>Metformin Hydrochloride</td><td>MET/B/01/19030070</td></tr>
<tr><td colspan="2">working standards</td></tr>
<tr><td>Sitagliptin Phosphate</td><td>1612903</td></tr>
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<tr><td>Metformin HCl</td><td>1396309</td></tr>
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<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 5 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Gvia M XR 50mg/500mg Tablets. The SOP mentions the details of master formulation & manufacturing method for both Gvia M XR 50mg/500mg. Copies of stability protocols have also been submitted for Gvia M XR 50mg/500mg Tablets.
The master formulation and manufacturing method mentioned in development protocol is same as that of reference product.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:
<table>
<tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr>
<tr><td>19SB-121-01</td><td>2500 Tablets</td><td>07-2019</td></tr>
<tr><td>19SB-122-02</td><td>2500 Tablets</td><td>07-2019</td></tr>
<tr><td>19SB-123-03</td><td>2500 Tablets</td><td>07-2019</td></tr>
</table>
As per submitted record all the activities of manufacturing i.e. dispensing, granulation, drying, compression & coating has been performed in PD lab.</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of stability batches.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 30-07-2019 to 29-02-2020.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Sitagliptin Phosphate USP (M-20190127-D01-M06-08) along with chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs from manufacturer M/s Fuxin Long Rui</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Pharmaceutical & supplier M/s Shenyang Vast Pharm Tech Co Ltd.
Metformin Hydrochloride USP (batch # MET/B/01/19030070) along with chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs from M/s Abhilash Chemicals</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-151 issued on 31-07-2019) for Gvia M XR 50mg/500mg Tablet along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (40°C± 2°C, 75% ±5%)and 9 months Real Time Stability Study (30°C+2°C, 65+5%) Data of 03 Batches of Sitagliptin Phosphate from M/s M/s Fuxin Long Rui Pharmaceutical

The firm has submitted photocopy of 06 Months Accelerated (40°C± 2°C, 75% ±5%)and 5 Years Real Time Stability Study (30°C+2°C, 65+5%) Data of 03 Batches of Metformin HCl from M/s Abhilash Chemicals.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Gvia M XR Tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product (Gvia M XR Tablets) is similar to that of innovator’s product i.e. JANUMET XR Tablet and also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/33) & reports dated 06-12-2019. The details of reference product & Sample product are as follows:
<table>
<tr><th>feature</th><th>Reference product</th><th>Product of M/S Genix Pharma</th></tr>
<tr><td>Brand name</td><td>JANUMET XR Tablet</td><td>GVIA M XR Tablets</td></tr>
<tr><td>Batch No</td><td>R034470</td><td>19SB-121-01</td></tr>
<tr><td>Expiry Date</td><td>07-2020</td><td>07-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
i. pH 0.1N HCl buffer
ii. pH 4.5 Acetate buffer
iii. pH 6.8 Phosphate buffer
In pH 0.1 N HCl buffer similarity factory is N/A.
In pH 4.5 Acetate buffer similarity factory is 83.288.
In pH 6.8 Phosphate buffer similarity factory is 73.818.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports of stability studies of applied formulation.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of GVIA-M XR 50/500mg Tablets with Innovator’s specifications by M/s Genix Pharma (Pvt.) Ltd. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
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Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
124.	**Genix Pharma (Pvt.) Ltd.** Karachi	GVIA-M XR Tablets Each extended-Release tablet contains: Sitagliptin Phosphate eq. to Sitagliptin ……50mg Metformin Hydrochloride USP……1000mg (Innovator's Specifications)	Form 5 Dy no 26429 01-08-2018, Fee: 20,000/- As per SRO 10's, 14's, 20's, 30's,	Janumet XR Tablets 50mg+1000mg, M/s Merck Sharp and Dohme Firm is operating at acceptable level of GMP compliance as per inspection dated 16-02-2018	**Deferred for submission of stability data and relevant documents.** (M-286th)

STABILITY STUDY DATA(VI)

Drug	GVIA-M XR 50mg+1000mg Tablets		
Name of Manufacturer	Genix Pharma (Pvt.) Ltd.		
Manufacturer of API	Fuxin long Rui pharmaceuticals & Abhilash Chemicals		
API Lot No.	M-20190127-D01-M06-08 & MET/B/01/19030070		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	**Accelerated:** 40°C ± 2°C / 75% ± 5%RH **Real Time:** 30°C ± 2°C / 65% ± 5%RH		
Time Period	**Accelerated:** 06 months **Real Time:** 06 months		
Frequency	**Accelerated:** 0, 1, 2,3,4 & 6 (Months) **Real Time:** 3,6 (Months)		
Batch No.	**18SB-118-01**	**18SB-119-02**	**18SB-120-03**
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	05-08-2019	05-08-2019	05-08-2019
No. of Batches	03		
Date of Submission	20-04-2020		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr. No.	Documents to Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Yes**
3.	Protocols followed for conduction of stability study and details of tests.	**Yes**
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory	**Yes**

	reports, data sheets etc.	
5.	Documents confirming import of API etc.	Copy of Form 7 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 16-04-2019, for the import of Sitagliptin Phosphate from the M/s Shenyang Vast Pharmatec Co Ltd, China, manufactured by Fuxin Long Rui Pharmaceutical CO.,Ltd has been submitted. Copy of Commercial Invoice (invoice no. SY190404-C) dated attested by ADC (Karachi) dated 18-04-2019 has been submitted. Copy of Form 7 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 18-03-2019, for the import of Metformin HCl from the M/s Abhilash Chemicals And Pharmaceuticals Taminadu, India has been submitted. Copy of Commercial Invoice (invoice no. GSTE-189/2018-19) dated 21-03-2019 attested by ADC (Karachi) dated 21/03/19 has been submitted.
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7.	Commitment to continue real time stability study till assigned shelf life of the product.	**Yes**
8.	Commitment to follow Drug Specification Rules, 1978.	**Yes**

REMARKS OF EVALUATOR
(AD PEC-I)

1. GMP of API Certificates of the concerned manufacturer is available.
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Version no: 01
Copy of “Vendor’s Audit form” filled for Fuxin long pharmaceutical company Ltd. & Abhilash Chemicals And Pharmaceuticals Taminadu, India dated 10-02-2019Attached.</td></tr>
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Metformin Hydrochloride USP (batch # MET/B/01/19030070) along with chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs from M/s Abhilash Chemicals</td></tr>
</table>

<table>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-148 issued on 24-07-2019) for Gvia M XR 50mg/1000mg Tablet along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (40°C± 2°C, 75% ±5%)and 9 months Real Time Stability Study (30°C+2°C, 65+5%) Data of 03 Batches of Sitagliptin Phosphate from M/s M/s Fuxin Long Rui Pharmaceutical

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<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/33) & reports dated 06-12-2019. The details of reference product & Sample product are as follows:
<table>
<tr><th>feature</th><th>Reference product</th><th>Product of M/S Genix Pharma</th></tr>
<tr><td>Brand name</td><td>JANUMET XR Tablet</td><td>GVIA M XR Tablets</td></tr>
<tr><td>Batch No</td><td>S009514</td><td>19SB-118-01</td></tr>
<tr><td>Expiry Date</td><td>11-2020</td><td>07-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
i. pH 0.1N HCl buffer
ii. pH 4.5 Acetate buffer
iii. pH 6.8 Phosphate buffer
In pH 0.1 N HCl buffer similarity factory is 73.785.
In pH 4.5 Acetate buffer similarity factory is 60.862.
In pH 6.8 Phosphate buffer similarity factory is 77.184.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of GVIA-M XR 50/500mg Tablets with Innovator’s specifications by M/s Genix Pharma (Pvt.) Ltd. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
M/s Indus Pharma (Pvt.) Ltd. 26-27 &63-67, Sector 27, Korangi Industrial Area 74900., Karachi.	Exilant 30mg Capsule Each HPMC capsule contains:- Dual Delayed Release Dexlansoprazole pellets 23% eq to Dexlansoprazole ……30mg	Form 5-D Dairy No. 6970 dated 19-02-2020 Rs.100,000/- dated 19-02-2019 As per DPC	Dexilant Delayed Release Capsule 30mg of USFDA approved Last inspection was conducted on16-08-2017 and report concludes that firm was considered to be operating at an	Source of pellets is Murli kirishna pharma Pvt. Ltd., Maharashtra, India

STABILITY STUDY DATA(VI)

Drug	Exilant 30mg Capsule		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Ltd. 26-27 & 63-67, Sector 27, Korangi Industrial Area 74900., Karachi.		
Manufacturer of API	M/s Murli Krishan Pharma (Pvt) Ltd India		
API Lot No.	PDL/DEF-1-271118		
Description of Pack (Container closure system)	Alu Alu Blister strips		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	TR-01/DEXL-30	TR-02/DEXL-30	TR-03/DEXL-30
Batch Size	2,500 Capsules	2,500 Capsules	2,500 Capsules
Manufacturing Date	26-05-2019	26-05-2019	26-05-2019
Date of Initiation	30-05-2019	30-05-2019	30-05-2019
No. of Batches	03		
Date of Submission	13-02-2020		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # PDL/DEF-1-271118) from M/s Murli Krishan Pharma (Pvt) Ltd India has been submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate for M/s Murli Krishan Pharma (Pvt) Ltd India issued by Food and Drug Administration, (Maharashtra state) is submitted. It is valid until 3 April 2022.
3.	Protocols followed for conduction of stability	Yes
	Study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Dexlansoprazole Pellets 23% w/w attested by ADC DRAP, Karachi dated 24-01-2019.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 3-03-2019 vide diary no.3331

Administrative Portion	
Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Dexilant 60mg Capsules (Dexlansoprazole)", which was presented in 293rd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Indus Pharma (Pvt.) Ltd., Karachi. **Date of inspection**: 14-03-2019 According to inspection report, following points were confirmed. The firm has 21CFR compliant HPLC software. The firm has audit trail reports available.
Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Dexlansoprazole Pellets 23% w/w attested by ADC DRAP, Karachi dated 24-01-2019.
Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Murli Krishan Pharma (Pvt) Ltd India issued by Food and Drug Administration, (Maharashtra state) is submitted and is valid till 3 April 2022.
List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
Production Data	
Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Dexlansoprazole Capsule 30mg".

<table>
<tr><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>TR-01/DEXL-30</td><td>2500 Tablets</td><td>26-05-2019</td></tr><tr><td>TR-02/DEXL-30</td><td>2500 Tablets</td><td>26-05-2019</td></tr><tr><td>TR-03/DEXL-30</td><td>2500 Tablets</td><td>26-05-2019</td></tr></table></td></tr>
<tr><td>Record of remaining quantities of stability batches.</td><td><table><tr><th>Trial No of</th><th>Total no. Capsules used for testing</th><th>Tablets Quantities For testing of tablets</th></tr><tr><td></td><td>stability</td><td></td></tr><tr><td></td><td>testing</td><td></td></tr><tr><td>TR-01/DEXL-30</td><td>37packs</td><td>41 packs 96 packs</td></tr><tr><td>TR-02/DEXL-30</td><td>37packs</td><td>41 packs 96 packs</td></tr><tr><td>TR-03/DEXL-30</td><td>37packs</td><td>41 packs 96 packs</td></tr></table></td></tr>
<tr><td colspan="2">QA / QC DATA</td></tr>
<tr><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 27-05-2019 to 30-11-2019</td></tr>
<tr><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Dexlansoprazole DDR Pellets.</td></tr>
<tr><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Dexlansoprazole Capsules 30mg” along with Stability Study Reports.</td></tr>
<tr><td>Reports of stability studies of API from Manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 36 months Long term Stability Study Data of 03 Batches from for M/s Murli Krishan Pharma (Pvt) Ltd India.</td></tr>
<tr><td>Analysis reports for excipients used.</td><td>No excipients is used</td></tr>
<tr><td>Drug-excipients compatibility studies.</td><td>N/A</td></tr>
<tr><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution for “Dexlansoprazole Capsules 30mg & Dexilant Capsules 30mg” and concludes that both, reference product and test product shows behavior in recommended medium (i.e, HCI Buffer pH 1.2, Phosphate Buffer pH 5.5, Acetate Buffer pH 4.5 and Phosphate Buffer pH7.0) and more than 85% release in Phosphate Buffer pH 7.0 medium under similar conditions.
Hence dissolution profiles of Exilant 30mg capsule (test product) and Dexilant 30mg capsule (reference product) arc considered similar.</td></tr>
</table>

Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit Dexlansoprazole Capsules 30mg

Decision: Registration Board decided to approve registration of Exilant 30mg Capsule with Innovator's specifications by M/s Indus Pharma (Pvt.) Ltd. 26-27 &63-67, Sector 27, Korangi Industrial Area 74900, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name and address of manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
126.	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi	Treviamet XR Tablets 100mg + 1000mg Each extended release tablet contains: Sitagliptin Phosphate Monohydrate equivalent to Sitagliptin… 100mg Metformin HCl …. 1000mg Oral anti-hyperglycemic agents Manufacturer Specs.	Form 5D Dy no 1803 dated 14-12-2012 PKR 50,000/- 12-12-2012 Demanded price is Rs.169 per tablet. Pack of 14's and 30's	Janumet XR Tablets 100mg + 1000mg by Merck Sharp and Dohme USA. (**USFDA** Approved) Last GMP Inspection dated 16-12-2019 concluding acceptable level of GMP compliance status **Decision of 289th meeting: Deferred for submission of stability data**
	Remarks of the Evaluator:			

STABILITY STUDY DATA(VI)

Drug	Treviamet XR Tablets 100mg + 1000mg		
Name of Manufacturer	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi		
Manufacturer of API	Sitagliptin: M/s Fuxin Long Rui Pharmaceutical Co. Ltd., China Metformin HCl: M/s Wanbury Limited India		
API Lot No.	Sitagliptin: M-20170727-D03-M06-02, M-20180921-D04-M06-06 & M-20181222-D06-M06-03 Metformin HCl: MT18751217		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time : 30◦C ± 2◦C / 75% ± 5%RH Accelerated: 40◦C ± 2◦C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,1,2,3,4,6 (months)		
Batch No.	274DS03	274DS04	274DS05
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	12.03.2019	20.03.2019	01.04.2019
Date of Initiation	15-04-2019	15-04-2019	15-04-2019
No. of Batches	03		

Date of Submission		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Fuxin Long Rui Pharmaceutical Co. Ltd., China issued by Liao Ning Food and Drug Administration, China (Certificate # LN180002). The certificate is valid till 27-03-2021. Firm has submitted copy of GMP certificate of M/s Wanbury Limited India issued by Drugs Control Administration, India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice confirming import of 350 Kg Sitagliptin from M/s Fuxin Long Rui Pharmaceutical Co. Ltd., China dated 27-09-2017 for Batch No. M-20170727-D03-M06-02, 350 Kg Sitagliptin dated 10-12-2018 for Batch No. M-20180921-D04-M06-06 and 400 Kg Sitagliptin dated 25-01-2019 for Batch No. M-20181222-D06-M06-03. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
Administrative Portion		
1	Reference of last onsite panel inspection for instant dosage form conducted during last two years	Firm has referred to onsite inspection report of their product for Arcox (Etoricoxib) Tablets 90mg & 120mg on 17th September, 2018 and was presented in 286th Drug Registration Board meeting held on 14th – 16th November, 2018. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and

		monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2	Documents for the procurement of API with approval from DRAP (in case of import)	Firm has submitted ADC attested invoice confirming import of 350 Kg Sitagliptin from M/s Fuxin Long Rui Pharmaceutical Co. Ltd., China dated 27-09-2017 for Batch No. M-20170727-D03-M06-02, 350 Kg Sitagliptin dated 10-12-2018 for Batch No. M-20180921-D04-M06-06 and 400 Kg Sitagliptin dated 25-01-2019 for Batch No. M-20181222-D06-M06-03. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
3	Documents for the procurement of reference standard and impurity standards	Firm has submitted COA and invoice of reference standard.
4	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of GMP certificate of M/s Fuxin Long Rui Pharmaceutical Co. Ltd., China issued by Liao Ning Food and Drug Administration, China (Certificate # LN180002). The certificate is valid till 27-03-2021. Firm has submitted copy of GMP certificate of M/s Wanbury Limited India issued by Drugs Control Administration, India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
5	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation report of Sitagliptin and Metformin HCl, filled and signed by technical persons of the firm.
6	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API and reference standard.
7	Documents for the procurement of excipients used in product development	Firm has submitted documents for procurement of excipients used in formulation of applied product.
8	List of qualified staff involved in product development with relevant experience	Firm has provided list of qualified staff of product development section and R&D Analytical Laboratory comprising of 43 qualified staff.
Production Data		
9	Authorized Protocols/SOP for the development & stability testing of trial batches	Firm has submitted authorized stability protocols / SOP for development and stability testing of trial batches.
10	Complete batch manufacturing record of three stability batches	Firm has submitted copy of Batch Manufacturing Record for all the three stability batches.
11	Record of remaining quantities of stability batches	Firm has provided following remaining quantities for each batch: 274DS03 : 388 Tablets 274DS04 : 388 Tablets 274DS05 : 388 Tablets
QA/QC Data		
12	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing.
13	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted copy of method of analysis of FPP and complete record of testing of stability batches along with chromatograms, lab reports, raw data sheets etc.

15	Reports of stability studies of API from manufacturer.	Firm has submitted stability studies reports of three batches of Sitagliptin and Metformin HCl.
16	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in product development
17	Drug-excipients compatibility studies.	Firm has submitted that same excipients has been used as used by innovator 'Janumet XR Tablets 100mg + 1000mg'. However, there is only difference in the film-coating material. Therefore, Drug-excipients compatibility studies were not performed.
18	Record of comparative dissolution data.	Firm has submitted data of comparative dissolution profile (in Phosphate buffer pH 6.8) with the innovator brand (Janumet XR Tablets).
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Decision: Registration Board decided to approve registration of Treviamet XR Tablets 100mg + 1000mg with Innovator's specifications by M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi.Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
127.	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore	Diamant 10 mg tablet Each film coated tablet contain: Empagliflozin …10 mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Manufacturer's Specifications.	Form-5-D Dy. No: 1363 Dated. 10/3/2016 Rs.50,000/- (10/March/2016) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO	Jardiance Tablets (USFDA Approved) Last inspection was conducted on 08-08-2019 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance.	

STABILITY STUDY DATA(VI)

Drug	Diamant 10mg Tablet
Name of Manufacturer	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrail Area, Kot Lakhpat, Lahore
Manufacturer of API	**Empagliflozin :** Zheiiang Hongyuan Pharmaceutical Co. Ltd, Chem and API Industrial Zone, Linhai, Zhejiang, China
API Lot No.	**Empagliflozin:** 20170401
Description of Pack (Container closure system)	2x10's Tablets in Alu Alu and Aluminium Foil
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Accelerated: 06 Months Real Time: 22 Months
Frequency	Accelerated: 0,1, 2,3, 4, 6 (Month) Real Time: 0,3,6, 9, 12, 18, 22 (Months)

Batch No.	T001	T002	T003
Batch Size	0.45 kg	0.45 kg	0.45 kg
Manufacturing Date	3-2018	3-2018	3-2018
Date of Initiation	10-3-18	10-3-18	10-3-18
No. of Batches	03		
Date of Submission	13/12/18 (Dy. No. 12526)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Yes Lot no. 20170401 DOM:12-04-2017 Assay(anhy.): 99.8%
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Empagliflozin: Copy of GMP certificate issued to M/s Zhejiang Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou Drug Administration. Firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd. Issued by China Food and Drug Administration China. Firm has copy of a statement that Zhejiang Hongyuan Pharmaceutical Co. Ltd., is sub company of Zhejiang Material industry chemical group Co. Ltd. The GMP certificate bearing number ZJ20130070 has been verified from CFDA database that mentions bulk material; Empagliflozin
3.	Protocols followed for conduction of stability	Yes
	Study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Empagliflozin along with working standard and all impurity standards: Copy of approval of Import of Empagliflozin by ADC DRAP Lahore along with DHL is attached.. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir i.e., Sofosbuvir…400mg & Velpatasvir……100 mg", which was presented in 292nd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Wilshire Laboratories (Pvt) Ltd, Lahore **Date of inspection**: 23.05.2019.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of approval of Empagliflozin Import by ADC DRAP Lahore along with DHL invoice is attached.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has document confirming the imported Empagliflozin (API) with working Reference standard of the API and all impurity Standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, issued by Taizhou Drug Administration, is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Empagliflozin (Batch # 20170401) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, COA of reference standards and impurity standards submitted
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Empagliflozin 10mg Film Coated Tablet" & stability testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:

Batch No.	**Batch Size**	**Mfg. Date**
T001	0.450 kg (83 Packs)	03/18
T002	0.450 kg (83 Packs)	03/18
T003	0.450 kg (83 Packs)	03/18

11.	Record of remaining quantities of stability batches.	

		T001 T002 T003	186 186 187 187 187 187	NIL NIL NIL	
QA / QC DATA					
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product of initial six months.			
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for API i.e., Empagliflozin			
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Diamant 10mg Tablet" along with Stability Study Reports.			
15.	Reports of stability studies of API from Manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 06 months Long term Stability Study Data of 03 Batches (Z1215-170601, Z1215-170602 and Z1215-170603) from for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China,			
16.	Analysis reports for excipients used.	Lactose SD/DT, Microcrystalline Cellulose (Avicel 102), Hydroxy propyl cellulose, Crossceramellose Sodium, Aerosil 200, Magnesium Sterate. TC-117-220001 Yellow, RO Water,			
17.	Drug-excipients compatibility studies.	N/A			
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution for "Diamant 10mg Tablet & Jardiance 10mg Tablet (Eli Lilly)" and concludes that both, reference product and test product show behavior in recommended medium (i.e, buffer pH 6.8, buffer pH 4.5, 0.1N HCl and Water. Hence dissolution profiles of Jardiance 10mg Tablet (reference product) and Diamant 10 mg Tablet (test product) arc considered similar.			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Diamant 10mg Tablet.			
Remarks of the Evaluator(VI): The firm has submitted 6 months accelerated and 22 months real time stability studies data of 3 batches.					
Decision: Deferred for submission of valid GMP certificate of API manufacturer from concerned regulatory authority of the country of origin as submitted GMP certificate is not from provincial or federal authority.					

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
128.	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	Diamant 25 mg tablet Each film coated tablet contain: Empagliflozin …25mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Manufacturer's Specifications.	Form-5-D Dy. No: 1362 Dated. 10/3/2016 Rs.50,000/- (10/March/2016) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	Jardiance tablet 25 mg by M/s Boehringer Ingelheim (USFDA Approved). Last inspection was conducted on 08-08-2019 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance	

STABILITY STUDY DATA(VI)

Drug	Diamant 25 mg tablet		
Name of Manufacturer	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.		
Manufacturer of API	**Empagliflozin :** M/s Zhejing materials industry chemical group co. Ltd. 25 floor tower A, Zhongda plaza, Zhongshan road, Hangzhou china		
API Lot No.	**Empagliflozin:** 20170401		
Description of Pack (Container closure	2x10's Tablets in Alu Alu and Aluminium Foil		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Accelerated: 06 Months Real Time: 22 Months		
Frequency	Accelerated: 0,1, 2,3, 4, 6 (Month) Real Time: 0,3,6, 9, 12, 18, 22 (Months)		
Batch No.	T001	T002	T003
Batch Size	0.45 kg	0.45 kg	0.45 kg
Manufacturing Date	3-2018	3-2018	3-2018
Date of Initiation	3-3-18	3-3-18	3-3-18
No. of Batches	03		
Date of Submission	13/12/18 (Dy. No. 12527)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Yes.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate issued to M/s Zhejing Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou city no Zhejiang province

3.	Protocols followed for conduction of stability Study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Empagliflozin along with working standard and all impurity standards: Copy of approval of Import of Empagliflozin by ADC DRAP Lahore along with DHL is attached.. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 28-11-2019 vide diary no. -------

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir i.e., Sofosbuvir…400mg & Velpatasvir……100mg", which was presented in 292nd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Wilshire Laboratories (Pvt) Ltd, Lahore **Date of inspection:** 23.05.2019.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of approval of Empagliflozin Import by ADC DRAP Lahore along with DHL invoice is attached.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has document confirming the imported Empagliflozin (API) with working Reference standard of the API and all impurity Standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, issued by Taizhou Drug Administration, is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Empagliflozin (Batch # 20170401) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, COA of reference standards and impurity standards submitted
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of formulation of applied product

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Empagliflozin 25 mg Film Coated Tablet” &
stability testing of trial batches.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T001</td><td>0.450 kg (83 Packs)</td><td>03/18</td></tr>
<tr><td>T002</td><td>0.450 kg (83 Packs)</td><td>03/18</td></tr>
<tr><td>T003</td><td>0.450 kg (83 Packs)</td><td>03/18</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Quantities of tablets</th></tr>
<tr><td>T001</td><td>600</td><td>600</td><td>NIL</td></tr>
<tr><td>T002</td><td>450</td><td>450</td><td>NIL</td></tr>
<tr><td>T003</td><td>360</td><td>360</td><td>NIL</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product of initial six months.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Empagliflozin</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Diamant 25 mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from Manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 6 months Long term Stability Study Data of 03 Batches (Z1215-170601, Z1215-170602 and Z1215-170603) from for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China,</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>Lactose SD/DT, Microcrystalline Cellulose (Avicel 102), Hydroxy propyl cellulose, Crossceramellose Sodium, Aerosil 200, Magnesium Sterate. TC-117-220001 Yellow, RO Water,</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>N/A</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution for “Diamant 25mg Tablet & Jardiance 25mg Tablet (Eli Lilly)” and concludes that both, reference product and test product show behavior in recommended medium (i.e, buffer pH 6.8, buffer pH 4.5, 0.1N HCl and Water.
Hence dissolution profiles of Jardiance 25mg Tablet (Reference product) and Diamant 25 mg Tablet (Test product) arc considered similar.</td></tr>
</table>

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Diamant 25mg Tablet.

Remarks of the Evaluator:(VI)The firm has submitted 6 months accelerated and 22 months real time stability studies data of 3 batches.

Decision: Deferred for submission of valid GMP certificate of API manufacturer from concerned regulatory authority of the country of origin as submitted GMP certificate is not from provincial or federal authority.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
129.	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore	Diamant-M 5 mg/500 mg Tablet Each film coated tablet contain: Empagliflozin …5 mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Metformin HCl…..500 mg Manufacturer's Specifications.	Form-5-D Dy. No: ---- Dated. 22-10-2018 Rs.50,000/- (12/10/2018) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	SYNJARDY TABLET 5MG/500MG (USFDA Approved) Last inspection was conducted on 08-08-2019 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance.	

STABILITY STUDY DATA

Drug	Diamant-M 5 mg/500 mg Tablet		
Name of Manufacturer	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrail Area, Kot Lakhpat, Lahore		
Manufacturer of API	**Empagliflozin :** Zheiiang Hongyuan Pharmaceutical Co. Ltd, Chem and API Industrial Zone, Linhai, Zhejiang, China **Metformin HCl:** IPCA Laboratories Ltd, 48 Kandivali Industrial Estate, Madhya Pradesh		
API Lot No.	**Empagliflozin:** 20170401 **Metformin HCl:** 6417ML2RMI		
Description of Pack (Container closure	3 x10's Tablets in Alu Alu and Aluminium Foil		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Accelerated: 06 Months Real Time: 18 Months		
Frequency	Accelerated: 1, 2,3, 4, 6 (Month) Real Time: 3,6, 9, 12, 18, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	1.5 kg	1.5 kg	1.5 kg
Manufacturing Date	01-18	01-18	01-18

Date of Initiation	18-01-18	18-01-18	18-01-18
No. of Batches	03		
Date of Submission	10/01/2020 (_____)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	**Empagliflozin:** Yes Lot no. 20170401 DOM:12-04-2017 Assay(anhy.): 99.8% from Zheiiang Hongyuan Pharmaceutical Co. Ltd, submitted **Metformin HCl:** Yes Lot no. 6417ML2RMI DOM: Dec-2016 Assay(anhy.): 99.5 % from IPCA Labs submitted
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate issued to M/s Zhejiang Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou Drug Administration. Firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd. Issued by China Food and Drug Administration China. Firm has copy of a statement that Zhejiang Hongyuan Pharmaceutical Co. Ltd., is sub company of Zhejiang Material industry chemical group Co. Ltd. **Metformin HCl:** Copy of GMP certificate issued to M/s IPCA Labs Ltd. The said certificate has been issued by Licensing Authority Food & Drug Administration Madhya Pradesh, India
3.	Protocols followed for conduction of stability	Yes
	Study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets	Yes
5.	Documents confirming import of API etc.	**Empagliflozin along with working standard and all impurity standards:** Copy of approval of Import of Empagliflozin by ADC DRAP Lahore along with DHL is attached. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017 **Metformin HCl along with working standard and all impurity standards:**.The firm has submitted copy of commercial invoice for the purchase of Metformin HCl attested by ADC DRAP, Lahore dated 02-01-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 10-01-2020 vide diary no.

	Administrative Portion	
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir i.e., Sofosbuvir…400mg & Velpatasvir……100 mg", which was presented in 292nd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Wilshire Laboratories (Pvt) Ltd, Lahore **Date of inspection**: 23.05.2019.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice & DHL for the purchase of Empagliflozin along with Copy of approval of Import of Empagliflozin by ADC DRAP Lahore is attached. ADC Lahore DRAP attested Commercial invoice of Metformin HCl has also been submitted.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has document confirming the imported Empagliflozin & Metformin HCl (API), working Reference standard of the API and all impurity Standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, issued by Taizhou Drug Administration, and GMP Certificate for IPCA Labs Ltd issued by Licensing Authority Food & Drug Administration Madhya Pradesh is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Empagliflozin (Batch # 20170401) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, COA of reference standards and impurity standards submitted Copy of COA of Metformin HCl (Lot # 6417ML2RMI) from M/s IPCA Labs Ltd, India COA of reference standards and impurity standards submitted
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Diamant-M 5 mg/500 mg Film Coated Tablet" & stability testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:

Batch No.	Batch Size	Mfg. Date
T001	1.5 kg	1/18
T002	1.5 kg	1/18
T003	1.5 kg	1/18

11.	Record of remaining quantities of stability batches.	**Trial No of stability testing** / **Total no. Tablets For testing** / **Tablets used for Quantities of tablets** T001 600 46 T002 600 46 1744 T003 600 46 1711 1743
	QA / QC DATA	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product of initial six months.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for API i.e., Empagliflozin & Metformin HCl
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Diamant-M 5 mg/500 mg Tablet" along with Stability Study Reports.
15.	Reports of stability studies of API from Manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 06 months Long term Stability Study Data of 03 Batches (Z1215-170601, Z1215-170602 and Z1215-170603) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, for Empagliflozin. Also submitted photocopy of 06 months Accelerated and 60 months Long term Stability Study Data of 03 Batches (9002ML2RMI, 9003ML2RMI, 9004ML2RMI,) from M/s IPCA Labs Ltd, India for Metformin HCl.
16.	Analysis reports for excipients used.	Copovidone, Starch, Aerosil, Magnesium Stearate, TC-117-220002 Yellow, RO water
17.	Drug-excipients compatibility studies.	N/A
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution for "Diamant-M 5.0mg/500mg Tablets Wilshire Pharma) & (Synjardy 5.0mg/500mg Tablets – Eli-Lilly) exhibited Similar Dissolution Profile in all dissolution medium 0.1N HCl, Buffer pH - 4.5, Buffer pH 6.8 and Water. So Both Products are equivalent in nature of Content Release pattern "In Vitro Comparative Dissolution Studies' has performed successfully.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Diamant-M 5 mg/500 mg Tablet
Remarks of the Evaluator:(VI) The firm has submitted 6 months accelerated and 18 months real time stability studies data of 3 batches.		
Decision: Deferred for submission of valid GMP certificate of API manufacturer from concerned regulatory authority of the country of origin as submitted GMP certificate is not from provincial or federal authority.		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
130.	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore	Diamant-M 5 mg/1000 mg Tablet Each film coated tablet contain: Empagliflozin …5 mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Metformin HCl…..1000 mg Manufacturer's Specifications.	Form-5-D Dy. No: ---- Dated. 22-10-2018 Rs.50,000/- (12/10/2018) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	SYNJARDY TABLET 5MG/1000MG (USFDA Approved Last inspection was conducted on 08-08-2019 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance.	

STABILITY STUDY DATA(VI)

Drug	Diamant-M 5 mg/1000 mg Tablet		
Name of Manufacturer	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrail Area, Kot Lakhpat, Lahore		
Manufacturer of API	**Empagliflozin :** Zheiiang Hongyuan Pharmaceutical Co. Ltd, Chem and API Industrial Zone, Linhai, Zhejiang, China **Metformin HCl:** IPCA Laboratories Ltd, 48 Kandivali Industrial Estate, Madhya Pradesh		
API Lot No.	**Empagliflozin:** 20170401 **Metformin HCl:** 6417ML2RMI		
Description of Pack (Container closure	3 x10's Tablets in Alu Alu and Aluminium Foil		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Accelerated: 06 Months Real Time: 18 Months		
Frequency	Accelerated: 1, 2,3, 4, 6 (Month) Real Time: 3,6, 9, 12, 18, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	3.0 kg	3.0 kg	3.0 kg
Manufacturing Date	01-18	01-18	01-18
Date of Initiation	17-02-18	17-02-18	17-02-18
No. of Batches	03		
Date of Submission	07/01/2020 (_____)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status

1.	COA of API	**Empagliflozin:** Yes Lot no. 20170401 DOM:12-04-2017 Assay(anhy.): 99.8% from Zheiiang Hongyuan Pharmaceutical Co. Ltd, submitted **Metformin HCl:** Yes Lot no. 6417ML2RMI DOM: Dec-2016 Assay(anhy.): 99.5 % from IPCA Labs submitted
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate issued to M/s Zhejiang Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou Drug Administration. Firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd. Issued by China Food and Drug Administration China. Firm has copy of a statement that Zhejiang Hongyuan Pharmaceutical Co. Ltd., is sub company of Zhejiang Material industry chemical group Co. Ltd. **Metformin HCl:** Copy of GMP certificate issued to M/s IPCA Labs Ltd. The said certificate has been issued by Licensing Authority Food & Drug Administration Madhya Pradesh, India
3.	Protocols followed for conduction of stability Study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets	Yes
5.	Documents confirming import of API etc.	**Empagliflozin along with working standard and all impurity standards:** Copy of approval of Import of Empagliflozin by ADC DRAP Lahore along with DHL is attached. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017 **Metformin HCl along with working standard and all impurity standards:**.The firm has submitted copy of commercial invoice for the purchase of Metformin HCl attested by ADC DRAP, Lahore dated 02-01-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: Date of submission: 07-01-2020 vide diary no. -------		
Administrative Portion		

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir i.e., Sofosbuvir…400mg & Velpatasvir……100 mg", which was presented in 292nd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Wilshire Laboratories (Pvt) Ltd, Lahore **Date of inspection**: 23.05.2019.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice & DHL for the purchase of Empagliflozin along with Copy of approval of Import of Empagliflozin by ADC DRAP Lahore is attached. ADC Lahore DRAP attested Commercial invoice of Metformin HCl has also been submitted.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has document confirming the imported Empagliflozin & Metformin HCl (API), working Reference standard of the API and all impurity Standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, issued by Taizhou Drug Administration, and GMP Certificate for IPCA Labs Ltd issued by Licensing Authority Food & Drug Administration Madhya Pradesh is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Empagliflozin (Batch # 20170401) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, COA of reference standards and impurity standards submitted. Copy of COA of Metformin HCl (Lot # 6417ML2RMI) from M/s IPCA Labs Ltd, India COA of reference standards and impurity standards submitted
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Diamant-M 5 mg/1000 mg Film Coated Tablet" &stability testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:

Batch No.	Batch Size	Mfg. Date
T001	3.0 kg	1/18
T002	3.0 kg	1/18
T003	3.0 kg	1/18

11.	Record of remaining quantities of stability batches.	

Trial No of stability	Total no. Tablets Tablets For testing	Tablets used for of tablets

		testing T001 600 46 1733 T002 600 46 1742 T003 600 46 1732
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product of initial six months.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for API i.e., Empagliflozin & Metformin HCl
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Diamant-M 5 mg/10000 mg Tablet" along with Stability Study Reports.
15.	Reports of stability studies of API from Manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 06 months Long term Stability Study Data of 03 Batches (Z1215-170601, Z1215-170602 and Z1215-170603) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, for Empagliflozin. Also submitted photocopy of 06 months Accelerated and 60 months Long term Stability Study Data of 03 Batches (9002ML2RMI, 9003ML2RMI, 9004ML2RMI,) from M/s IPCA Labs Ltd, India for Metformin HCl.
16.	Analysis reports for excipients used.	Copovidone, Starch, Aerosil, Magnesium Stearate, TC-117-220002 Yellow, RO water
17.	Drug-excipients compatibility studies.	N/A
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution for "Diamant-M 5.0mg/1000mg Tablets Wilshire Pharma) & (Synjardy 5.0mg/1000mg Tablets – Eli-Lilly) exhibited Similar Dissolution Profile in all dissolution medium 0.1N HCl, Buffer pH - 4.5, Buffer pH 6.8 and Water. So Both Products are equivalent in nature of Content Release pattern "In Vitro Comparative Dissolution Studies' has performed successfully.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Diamant-M 5 mg/1000 mg Tablet
(VI)	The firm has submitted 6 months accelerated and 18 months real time stability studies data of 3 batches.	
Decision: Deferred for submission of valid GMP certificate of API manufacturer from concerned regulatory authority of the country of origin as submitted GMP certificate is not from provincial or federal authority.		

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
131.	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore	Diamant-M 12.5 mg/500 mg Tablet Each film coated tablet contain: Empagliflozin …12.5 mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Metformin HCl…..500 mg Manufacturer's Specifications.	Form-5-D Dy. No: ---- Dated. 22-10-2-018 Rs.50,000/- (12/10/2018) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	SYNJARDY TABLET 12.5 MG/500MG (USFDA Approved) Last inspection was conducted on 08-08-2019 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance.	

STABILITY STUDY DATA(VI)

Drug	Diamant-M 12.5 mg/500 mg Tablet		
Name of Manufacturer	M/s Wilshire Laboratories (Pvt.) Ltd. 124/1, Quaid-e-Azam Industrail Area, Kot Lakhpat, Lahore		
Manufacturer of API	**Empagliflozin :** Zheiiang Hongyuan Pharmaceutical Co. Ltd, Chem and API Industrial Zone, Linhai, Zhejiang, China **Metformin HCl:** IPCA Laboratories Ltd, 48 Kandivali Industrial Estate, Madhya Pradesh		
API Lot No.	**Empagliflozin:** 20170401 **Metformin HCl:** 6417ML2RMI		
Description of Pack (Container closure	3 x10's Tablets in Alu Alu and Aluminium Foil		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Accelerated: 06 Months Real Time: 18 Months		
Frequency	Accelerated: 1, 2,3, 4, 6 (Month) Real Time: 3,6, 9, 12, 18, 24 (Months)		
Batch No.	T001	T002	T003
Batch Size	1.5 kg	1.5 kg	1.5 kg
Manufacturing Date	01-18	01-18	01-18
Date of Initiation	07-02-18	07-02-18	07-02-18
No. of Batches	03		
Date of Submission	07/01/2020 (_____)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status

1.	COA of API	**Empagliflozin:** Yes Lot no. 20170401 DOM:12-04-2017 Assay(anhy.): 99.8% from Zheiiang Hongyuan Pharmaceutical Co. Ltd, submitted **Metformin HCl:** Yes Lot no. 6417ML2RMI DOM: Dec-2016 Assay(anhy.): 99.5 % from IPCA Labs submitted
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate issued to M/s Zhejiang Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou Drug Administration. Firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd. Issued by China Food and Drug Administration China. Firm has copy of a statement that Zhejiang Hongyuan Pharmaceutical Co. Ltd., is sub company of Zhejiang Material industry chemical group Co. Ltd. **Metformin HCl:** Copy of GMP certificate issued to M/s IPCA Labs Ltd. The said certificate has been issued by Licensing Authority Food & Drug Administration Madhya Pradesh, India
3.	Protocols followed for conduction of stability	Yes
	Study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets	Yes
5.	Documents confirming import of API etc.	**Empagliflozin along with working standard and all impurity standards:** Copy of approval of Import of Empagliflozin by ADC DRAP Lahore along with DHL is attached. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017 **Metformin HCl along with working standard and all impurity standards:**.The firm has submitted copy of commercial invoice for the purchase of Metformin HCl attested by ADC DRAP, Lahore dated 02-01-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: Date of submission: 07-01-2020 vide diary no. -------		
Administrative Portion		

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir i.e., Sofosbuvir…400mg & Velpatasvir……100 mg", which was presented in 292nd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Wilshire Laboratories (Pvt) Ltd, Lahore **Date of inspection**: 23.05.2019.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice & DHL for the purchase of Empagliflozin along with Copy of approval of Import of Empagliflozin by ADC DRAP Lahore is attached. ADC Lahore DRAP attested Commercial invoice of Metformin HCl has also been submitted.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has document confirming the imported Empagliflozin & Metformin HCl (API), working Reference standard of the API and all impurity Standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of API/ DML/GMP Certificate for M/s Zhejiang Hongyun pharmaceuticals co. Ltd, issued by Taizhou Drug Administration, and GMP Certificate for IPCA Labs Ltd issued by Licensing Authority Food & Drug Administration Madhya Pradesh is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Empagliflozin (Batch # 20170401) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, COA of reference standards and impurity standards submitted Copy of COA of Metformin HCl (Lot # 6417ML2RMI) from M/s IPCA Labs Ltd, India COA of reference standards and impurity standards submitted
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Diamant-M 12.5 mg/500 mg Film Coated Tablet" & stability testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** T001 / 1.5 kg / 1/18 T002 / 1.5 kg / 1/18 T003 / 1.5 kg / 1/18
11.	Record of remaining quantities of stability batches.	**Trial No of Tablets** / **Total no. Tablets used for** / **Tablets Quantities**

			For testing of tablets stability testing		
		T001 T002	600 600	46 46	1729 1761
		T003	600	46	1766
QA / QC DATA					
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product of initial six months.			
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for API i.e., Empagliflozin & Metformin HCl			
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Diamant-M 12.5 mg/500 mg Tablet" along with Stability Study Reports.			
15.	Reports of stability studies of API from Manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 06 months Long term Stability Study Data of 03 Batches (Z1215-170601, Z1215-170602 and Z1215-170603) from M/s Zhejiang Hongyun pharmaceuticals co. Ltd, China, for Empagliflozin. Also submitted photocopy of 06 months Accelerated and 60 months Long term Stability Study Data of 03 Batches (9002ML2RMI, 9003ML2RMI, 9004ML2RMI,) from M/s IPCA Labs Ltd, India for Metformin HCl.			
16.	Analysis reports for excipients used.	Copovidone, Starch, Aerosil, Magnesium Stearate, TC-117-220002 Yellow, RO water			
17.	Drug-excipients compatibility studies.	N/A			
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution for "Diamant-M 12.5mg/500mg Tablets Wilshire Pharma) & (Synjardy 12.5mg/500mg Tablets – Eli-Lilly) exhibited Similar Dissolution Profile in all dissolution medium 0.1N HCl, Buffer pH - 4.5, Buffer pH 6.8 and Water. So Both Products are equivalent in nature of Content Release pattern "In Vitro Comparative Dissolution Studies' has performed successfully.			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Diamant- M 12.5 mg/500 mg Tablets.			
Decision: Deferred for submission of valid GMP certificate of API manufacturer from concerned regulatory authority of the country of origin as submitted GMP certificate is not from provincial or federal authority.					

Agenda of Evaluator PEC-IV

Case no. 01: Deferred COVID-19 cases:
1. Azithromycin Tablet 250mg:
Composition:
Each Film coated tablet contains:
Azithromycin as dihydrate…….250mg
Availability in RRAs:
MHRA Approved
ME too status:
" Azic 250mg Tablet by M/s Nabi Qasim Reg # 055583
Specifications:
USP

Sr. No.	Name of applicant	Brand Name with composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Previous decision (M-295)	Evaluation by PEC	Decision
132.	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Aziwiz 250mg Tablet Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12462 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Renewal of DML recommended in inspection dated 13-2-2019 Film coating step not mentioned in manufacturing method	Deferred for clarification of coating in manufacturing outline.	Firm submitted revised method of manufacturing With coating step.	**Approved.**
133.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mycin Tablet 250mg Each tablet contains: Azithromycin as Azithromycin dihydrate…250mg	Form-5A Dy.No 15354 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per DRAP Policy 6's	The firm was inspected on 12/05/18 concluding Good level of cGMP. Firm applied on Form-5A (for imported drug) while the drug will locally manufacture.	Deferred for submission of application on approved format of Form-5	Firm submitted application of form 5	**Approved.**
134.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Dynamycin 250mg Tablet Each Tablet Contains: Azithromycin…250mg	Dy.No. 11727 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	As per SRO	Last GMP inspection report dated 04-12-2018 recommends grant of DML Firm applied for uncoated tablet of azithromycin rather film coated azithromycin (as dihydrate)	Deferred for revision of formulation as per reference alongwith applicable fee	Firm submitted that they have already applied as per innovator product which is film coated and verified from dossier	**Approved.**

1. Azithromycin Tablet 250mg:
Composition:
Each Film coated tablet contains:
Azithromycin as dihydrate…….500mg
Availability in RRAs:
MHRA Approved
ME too status:
" Azic 500mg Tablet by M/s Nabi Qasim Reg # 055584
Specifications:
USP

Sr. No.	Name of applicant	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Previous decision (M-295)	Evaluation by PEC	Decision
135.	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad	Zaracin 500mg Tablet Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg	Dy.No. 10735 dated 12/05/2020 Rs. 20,000/- dated 12-05-2020 Form 5	6's	GMP certificate issued on the basis of inspection conducted on 01/03/2019. Step of film coating not mentioned in manufacturing method	Deferred for clarification of step of film coating in manufacturing I \vb tvb g method.	Firm submitted revised method of manufacturing With coating step.	**Approved**
136.	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Aziwiz 500mg Tablet Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12463 dated 03/06/2020 Rs. 20,000/- dated 03-06-2020 Form 5	10's	Renewal of DML recommended in the inspection dated 13-02-2019 Film coating step not mentioned in manufacturing method	Deferred for clarification of coating in manufacturing outline.	Firm submitted revised method of manufacturing With coating step.	**Approved**
137.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Cyzit 500mg Tablet Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11594 dated 20/05/2020 Rs. 20,000/- dated 19-05-2020 Form 5	6's 10's	GMP Certificate issued on 15-03-2018. Step of film coating not mentioned in manufacturing method	Deferred for clarification of coating in manufacturing outline.	Firm submitted revised method of manufacturing With coating step.	**Approved**
138.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Macazit 500mg Tablet Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11497 dated 19/05/2020 Rs. 20,000/- dated 19-05-2020 Form 5	6's 10's	03/05/2019 inspection dated. The panel recommended renewal of DML. Method of manufacturing not submitted	Deferred for submission of method of manufacturing.	Complete outline of method of manufacturing submitted.	**Approved**

Case no. 02 Registration applications for local manufacturing of (Human) drugs

a. New cases

139.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Dofen 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R& I & fee	Dy.No 8693 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	NSIADs
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	30's : As Per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen of (MHRA approved)
	Me-too status	Obsprufen 400mg Tablet by M/s OBS
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator [IV]	The firm change formulation from enteric coated to film coated with submission of fee Rs: 5000/- Deposit slip no #0788372, Dated: 02-06-2020
	Decision: Approved with innovator's specification.	
140.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cold Rest Tablet 60mg/120mg
	Composition	Each bilayer Tablet Contains: Fexofenadine HCL…60mg Pseudoephedrine HCL…120mg
	Diary No. Date of R& I & fee	Dy.No 8699 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-Histamine & Sympathomimetic agent.
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	TELFAST Decongestant of Sanofi Aventis (Approved in TGA Austraila)
	Me-too status	Fexet-D 60Mg/120Mg Tablets of Getz Pharma (Pvt.) Ltd, Karachi (Reg # 039099)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator [IV]	The firm change formulation from film coated to bilayer with submission of fee Rs: 5000/- Deposit slip no #0788374, Dated: 02-06-2020. As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivey note. Firm submitted IQ, OQ and PQ of bi-layered tablet machine.
	Decision: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
141.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Oricap 120mg Capsule
	Composition	Each Capsule Contains: Orlistat…120mg
	Diary No. Date of R& I & fee	Dy.No 7068 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Beacita 120mg Capsules of (MHRA approved)

	Me-too status	Orlisat 120mg Capsules by M/s Merck Sharp & Dhome,
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator IV	Source of pellets: Surge laboratories
	Decision: Deferred for submission of pellets data as per decision of Registration Board regarding stability of orlistat pellets.	
142.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	AD Forte Tablet 50mg/650mg
	Composition	Each Tablet Contains: Orphenadrine…50mg Paracetamol…650mg
	Diary No. Date of R& I & fee	Dy.No 8690 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Analgesic /Muscle Relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	15's, 100's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Wilgesic Forte Tablets M/s Wilson's Pharmaceuticals
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator IV	Firm change formulation as follows: Each Tablet Contains: Orphenadrine…35mg Paracetamol…450mg With submission of fee of RS; 5000/- Deposit slip no #0788373, Dated: 02-06-2020.
		Approval status of product in Reference Regulatory Authorities / **Norgesic by M/s iNova Pharmaceuticals, Australia(TGA)** Me-too status / SIC Tablets of M/s Shrooq Pharmaceuticals
	Decision: Deferred for following: **Revision of salt form of orphenadrine in applied formulation.** **Submission of differential fee of Rs. 15000/- for revision of strength of formulation.**	
143.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Amtel 5/80 mg Tablet
	Composition	Each bilayer uncoated Tablet Contains: Telmisartan…80mg Amlodipine as besylate…5mg
	Diary No. Date of R& I & fee	Dy.No 7075 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.

	Remarks of the Evaluator [IV]	• Firm change formulation from film coated to bilayer uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 0788370 dated: 02-06-2020 • As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivery note. Firm submitted IQ, OQ and PQ of bi-layered tablet machine.
	Decision: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
144.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Telmi-H 40/12.5mg Tablet
	Composition	Each bilayer uncoated Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 7069 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator [IV]	• Firm change formulation from film coated to bilayer uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 0788369 dated: 02-06-2020 • As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivery note. Firm submitted IQ, OQ and PQ of bi-layered tablet machine.
	Decision: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
145.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Telmi-H 80/12.5mg Tablet
	Composition	Each bilayer uncoated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 7825 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 80/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator [IV]	• Firm change formulation from film coated to bilayer uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 0788368 dated: 02-06-2020 • As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivery

		note. Firm submitted IQ, OQ and PQ of bi-layered tablet machine.
	Decision: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
146.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Telmi-H 80/25 mg Tablet
	Composition	Each bilayer uncoated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy.No 7896 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 80/25mg Tablet of M/S Tabros Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator [IV]	• Firm change formulation from film coated to bilayer uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 0788367 dated: 02-06-2020 • As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivery note. Firm submitted IQ, OQ and PQ of bi-layered tablet machine.
	Decision: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
147.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Dulox Capsule 30mg
	Composition	Each Capsule Contains: Duloxetine HCl(17 % enteric coated pellets)eq to Duloxetine …30mg
	Diary No. Date of R& I & fee	Dy.No 5875 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 30mg Capsule by M/s Martin Dow
	GMP status	As above
	Remarks of the Evaluator [IV]	Source of pellets: Vision
	Decision: Approved.	
148.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, K.P.K
	Brand Name +Dosage Form + Strength	Dulox Capsule 60mg
	Composition	Each Capsule Contains: Duloxetine HCl(17 % enteric coated pellets)eq to Duloxetine …60mg
	Diary No. Date of R& I & fee	Dy.No 5874 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 60mg Capsule by M/s Martin Dow
	GMP status	As above
	Remarks of the Evaluator IV	Source of pellets: Vision
	Decision: Approved.	
149.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma.Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Etob 90mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib …90mg
	Diary No. Date of R& I & fee	Dy.No. 9381 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Arcoxia 90 MG of (MHRA approved)
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator IV	Submitt Stability studies along with requisite documents and differential fee.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along differential fee.	
150.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma.Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Lide 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…….50mg
	Diary No. Date of R& I & fee	Dy.No. 9364 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 50mg Table M/s Helix Pharma
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator IV	
	Decision: Approved with innovator's specification.	
151.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma.Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Lide 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…….100mg
	Diary No. Date of R& I & fee	Dy.No. 9365 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)

	Me-too status	Nurosa 100mg Table M/s Helix Pharma
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
152.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma.Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Lide 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…….150mg
	Diary No. Date of R& I & fee	Dy.No. 9366 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Atcomid 150mg Tablet M/s Atco Lab
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
153.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma.Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Lide 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…….200mg
	Diary No. Date of R& I & fee	Dy.No. 9367 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 200mg Table M/s Helix Pharma
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
154.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Indu
	Brand Name +Dosage Form + Strength	Etira Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy.No. 9359 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Levetiracetam of (MHRA Approved)
	Me-too status	Letrawin Tablets 250mg of M/s Opal Laboratory

	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
155.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Loram 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…4mg
	Diary No. Date of R& I & fee	Dy.No. 9357 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	5's, 10's, 20's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg tablet (EMA approved)
	Me-too status	Lorfix 4mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
156.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Loram 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy.No. 9358 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	5's, 10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
157.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Danon Tablets 8mg
	Composition	Each Film Coated Tablet Contains: Ondansetron HCl Dihydrate eq to Ondasetron…8mg
	Diary No. Date of R& I & fee	Dy.No. 9377 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Selective serotonin 5-HT3 receptor Antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zofran Of (USFDA Approved)
	Me-too status	Ondonix 8mg Tablet M/s Genix Pharma

	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
158.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Petra 325/37.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…325mg Tramadol Hcl…37.5mg
	Diary No. Date of R& I & fee	Dy.No. 9363 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
159.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Serna Tablets 50mg
	Composition	Each Film Coated Tablet Contains: Sertraline as Hcl…50mg
	Diary No. Date of R& I & fee	Dy.No. 9371 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti depressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zoloft Tablet Of (USFDA Approved)
	Me-too status	Ertalin 50 mg Tablets M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved	
160.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Sitamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate…50mg Metformin HCL…500mg
	Diary No. Date of R& I & fee	Dy.No. 9368 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	14's, 20's, & 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet tablets of (TGA approved)
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson

	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
161.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Sitamet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate…50mg Metformin HCL…1000mg
	Diary No. Date of R& I & fee	Dy.No. 9369 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	14's, 20's, & 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet tablets of (TGA approved)
	Me-too status	Silmax-M 50mg/1000mg Tablet by M/s High-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
162.	Name and address of manufacturer / Applicant	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Topet Tablets 25mg
	Composition	Each Film Coated Tablet Contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Dy.No. 9372 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's & 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Lowseiz 25mg Tablets of M/S Helix Pharma
	GMP status	Last GMP inspection conducted on 31-01-2018 and report concludes that firm was operating atfair level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
163.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Mevodip Tablet 5mg/80mg
	Composition	Each film coated Tablet Contains: Amoldipine besylate eq to Amlodipine.…5mg Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy.No. 10667 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)

	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
164.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Mevodip Tablet 5mg/160mg
	Composition	Each film coated Tablet Contains: Amoldipine besylate eq to Amlodipine..…5mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy.No. 10668 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 5mg/160mg Tablet by M/s Vision Pharma
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
165.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Difu 250mg Tablet
	Composition	Each film coated Tablet Contains: Diflunisal……250mg
	Diary No. Date of R& I & fee	Dy.No. 10652 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflunisal 250mg of MHRA approved
	Me-too status	Dolobis-250 Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
166.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Difu 500mg Tablet
	Composition	Each film coated Tablet Contains: Diflunisal……500mg
	Diary No. Date of R& I & fee	Dy.No. 10653 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflunisal 500mg of MHRA approved
	Me-too status	Dolobis-500 Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	

167.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	D Tine 20mg Capsule
	Composition	Each hard gelatin capsule contains: Duloxetine as HCL(enteric coated pellets)…20mg
	Diary No. Date of R& I & fee	Dy.No. 10661 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's, 2 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 20mg Capsule by M/s Martin Dow
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Source of pellets : Vision
	Decision: Approved.	
168.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	D Tine 30mg Capsule
	Composition	Each hard gelatin capsule contains: Duloxetine as HCL(enteric coated pellets)…30mg
	Diary No. Date of R& I & fee	Dy.No. 10662 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's, 2 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 30mg Capsule by M/s Martin Dow
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Source of pellets : Vision
	Decision: Approved.	
169.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	D Tine 60mg Capsule
	Composition	Each hard gelatin capsule contains: Duloxetine as HCL (enteric coated pellets)…60mg
	Diary No. Date of R& I & fee	Dy.No. 10664 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's, 2 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 60mg Capsule by M/s Martin Dow
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Source of pellets : Vision
	Decision: Approved.	
170.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Erox 60mg Tablet

	Composition	Each film coatedTablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy.No. 10655 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	1 x10's, 2 x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 60 mg film-coated tablets of (MHRA approved)
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
171.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Febux 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R& I & fee	Dy.No. 10646 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40mg Tablet of (USFDA approved)
	Me-too status	Febuxin 40mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
172.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Febux 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Dy.No. 10647 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 80mg Tablet of (USFDA approved)
	Me-too status	Febuxin 80mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
173.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Prega 50mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy.No. 10644 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5

	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1x 14's: ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
174.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Prega 75mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…75mg
	Diary No. Date of R& I & fee	Dy.No. 10645 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
175.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Prega 100mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No. 10643 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 14's,: per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
176.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Quepine 25mg Tablet
	Composition	Each film coated Tablet Contains: Quetiapine as Fumarate …….25mg
	Diary No. Date of R& I & fee	Dy.No. 10641 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 25mg Tablet of M/s Nabiqasim

	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
177.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Quepine 100mg Tablet
	Composition	Each film coated Tablet Contains: Quetiapine as Fumarate …100mg
	Diary No. Date of R& I & fee	Dy.No. 10639 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 100mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
178.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Quepine 200mg Tablet
	Composition	Each film coated Tablet Contains: Quetiapine as Fumarate …200mg
	Diary No. Date of R& I & fee	Dy.No. 10642 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	SEROQUEL (of USFDA approved)
	Me-too status	Quit 200mg Tablets of M/s Navegal Labs, (Reg.# 068241)
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
179.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Exor-H 5/160/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 14301 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Hct Of (USFDA Approved)
	Me-too status	Exforge Hct Of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections

		" Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
180.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lemoxol Forte Tablet
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R& I & fee	Dy.No. 12695 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specifications	International Pharmacopoeia
	Pack size & Demanded Price	4's, 6's : As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified
	Me-too status	Artem Ds Plus Tablet by M/s Hilton Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
181.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Adzon Gel
	Composition	Each Gm Contains: Adapalene…1mg (0.1% w/w) Benzoyl Peroxide…25mg (2.5% w/w)
	Diary No. Date of R& I & fee	Dy.No. 14074 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15gm, 30gm, 45gm, 60gm & 90gm ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Epiduo gel of (USFDA Approved)
	Me-too status	Adalen e-B Gel of M/s Pharmatec (Reg#076683)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
182.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rota-12 1000mcg Injection
	Composition	Each ml Ampoule Contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No. 12669 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Vitamin b12
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml x 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytamen Injection 1000mcg Of (MHRA Approved)
	Me-too status	Cyfort Injection M/s Swiss Pharma

	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
183.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Feripro 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Deferiprone…500mg
	Diary No. Date of R& I & fee	Dy.No. 12671 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Iron Chelating Agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	FERRIPROX Of (USFDA Approved)
	Me-too status	Proxifer 500mg Tablets of M/s Nabiqasim Ind.(Reg# 045032)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
184.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	I Rot Tablet 5mg
	Composition	Each Tablet Contains: Folic Acid…5mg
	Diary No. Date of R& I & fee	Dy.No. 17447 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Vitamin B9
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,20's, 30-'s, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zal 5mg Tablets of M/s Alsons Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
185.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rogex 80mg Injection
	Composition	Each 2ml Contains: Gentamycin Sulphate Eq. to Gentamycin…80mg
	Diary No. Date of R& I & fee	Dy.No. 14295 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Aminoglycoside
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2ml x 5's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Gentamicin 40 mg/ml, solution for injection/infusion of MHRA approved

	Me-too status	Fengen Injection 80m of M/ Fynk Pharma Reg # 065892
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
186.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ketrox 2% w/v Lotion
	Composition	Each ml Contains: Ketoconazole…20mg
	Diary No. Date of R& I & fee	Dy.No. 14063 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Antifungal for topical use (Imidazole and triazole derivative)
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	60ml, 90ml :As per SRO
	Approval status of product in Reference Regulatory Authorities	Nizoral Anti-Dandruff Shampoo by M/s McNeil Products Limited (MHRA Approved)
	Me-too status	Ketonaz Lotion by M/s Sante (Reg#073453)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
187.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zefen 1mg Tablet
	Composition	Each Tablet Contains: Ketotifen Hydrogen Fumarate eq to Ketotifen……..1mg
	Diary No. Date of R& I & fee	Dy.No. 17454 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specification
	Pack size & Demanded Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZADITEN of (MHRA approved)
	Me-too status	Bronk 1 mg Tablet of Semos Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
188.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Benmox 100mg/5ml Liquid Suspension
	Composition	Each 5ml Contains: Mebendazole…100mg
	Diary No. Date of R& I & fee	Dy.No. 12711 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30ml:: As per SRO

	Approval status of product in Reference Regulatory Authorities	Vermox 100 mg/5 ml oral suspension of MHRA approved
	Me-too status	Mebizin Suspension of M/s Shrooq Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
189.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Maxotex 10mg Tablet
	Composition	Each Tablet Contains: Metoclopramide HCl eq to Metoclopramide (Anhydrous)…10mg
	Diary No. Date of R& I & fee	Dy.No. 17430 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Anti-dopaminergic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Maxolon 10mg Tablets of MHRA approved
	Me-too status	Faclomide 10mg Tablets of M/s Farm Aid Group
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
190.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dekzol 2% w/w Oral Gel
	Composition	Each Gm Contains: Miconazole…20mg
	Diary No. Date of R& I & fee	Dy.No. 14072 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Antiinfective/ Antiseptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Daktarin Oral Gel of MHRA approved
	Me-too status	Miconit Oral Gel 2% of M/s Bio-Labs (Reg. # 054776)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
191.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Gil 100mg Tablet
	Composition	Each Uncoated Tablet Contains: Modafinil…100mg
	Diary No. Date of R& I & fee	Dy.No. 12687 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Psychostimulants, agents used for adhd and nootropics (Centrally acting sympathomimetics)
	Type of Form	Form 5

	Finished product Specifications	USP
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Modafinil 100 mg tablets of MHRA approved
	Me-too status	Monalert 100mg Tablet of M/s Hilton Pharma Reg # 047170)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
192.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Gil 200mg Tablet
	Composition	Each Uncoated Tablet Contains: Modafinil…200mg
	Diary No. Date of R& I & fee	Dy.No. 12688 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Psychostimulants, agents used for adhd and nootropics (Centrally acting sympathomimetics)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Modafinil 200 mg tablets of MHRA approved
	Me-too status	Monalert 200mg Tablet of M/s Hilton Pharma (Reg # 047171)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
193.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vmax 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Penicillamine……250mg
	Diary No. Date of R& I & fee	Dy.No. 12680 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anti-rehumatic
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Penicillamine 250 mg film-coated tablets of MHRA approved
	Me-too status	Penicillamine 250mg Tablet of M/s Medisure Lab (083907)
	GMP status	Last GMP inspection conducted on 19-09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
194.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rifapen Forte Tablet
	Composition	Each Film Coated Tablet Contains: Rifampicin…….150mg Isoniazid…….75mg Ethambutol Hcl……..275mg

		Pyrazinamide…400mg
	Diary No. Date of R& I & fee	Dy.No. 14253 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Anti-tubercular drugs
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	50's, 80's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Rimstar, 150 mg/75 mg/400 mg/275 mg film- coated tablet. by M/s Sandoz (Swedish Medical Products Agency Approved)
	Me-too status	Myrin P Forte Tablets by M/s Wyeth, (Reg#027082)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
195.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rocept Injection 440mg/20ml
	Composition	Each Vial Contains: Trastuzumab…440mg
	Diary No. Date of R& I & fee	Dy.No. 14265 dated 07-03-2019 Rs.20,000/- 07-02-2019
	Pharmacological Group	Monoclonal antibody
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml x 1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	HERCEPTIN 440MG by M/s ROCHE
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Decision: Referred to Biological Drugs Division being Biological product.	
196.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Fox Tablet
	Composition	Each Uncoated Tablet Contains: Venlafaxine as Hcl…37.5mg
	Diary No. Date of R& I & fee	Dy.No. 12700 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	EFFEXOR of (USFDA approved)
	Me-too status	Venlor-37.5 Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 aAnd report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

197.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Warfix 5mg Tablet
	Composition	Each Tablet Contains: Warfarin Sodium…5mg
	Diary No. Date of R& I & fee	Dy.No. 17432 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Thromboembolic conditions
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	COUMADIN of USFDA approved
	Me-too status	Coagurin 5mg Tablets of M/s Atco Laboratories
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
198.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zincom 20mg Tablet
	Composition	Each Dispersible Tablet Contains: Zinc Sulphate Monohydrate Eq. to Elemental Zinc…20mg
	Diary No. Date of R& I & fee	Dy.No. 12684 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's : As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Zincfant Tablet 20 mg manufactured by Laboratoires Pharmaceutique s Rodael -France
	Me-too status	Zinxus Tablet of M/s Ferozsons
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
199.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clintop Gel
	Composition	Each gm Contains: Clindamycin as phosphate….10mg
	Diary No. Date of R& I & fee	Dy.No. 14073 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-infective
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10gm, 20gm : As per SRO
	Approval status of product in Reference Regulatory Authorities	RESIDERM 1%w/w GEL (MHRA approved)
	Me-too status	Sixil 10mg/g Gel of M/s Sigma Pharma (Reg # 079912)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

200.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ropim 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Ropinirole as Hcl…1mg
	Diary No. Date of R& I & fee	Dy.No. 12693 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP of USFDA approved
	Me-too status	Ronirol 1mg Tablets of M/s Hilton Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
201.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Desdine 5mg
	Composition	Each film coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 3862 dated 28-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	CLARINEX of USFDA approved
	Me-too status	Larinex Tablets of M/s Getz Pharma
	GMP status	GMP Inspection conducted on 12-07-2018 stated that most of the shortcomings pointed out during last inspection had been rectified by firm. Some advices were also given for further improvements & up-gradations & management showed positive approach towards compliance.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
202.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colistat 2 Million IU Powder for Solution for Injection
	Composition	Each Vial Contains: Colistimethate Sodium…2 Million IU
	Diary No. Date of R& I & fee	Dy.No 8526 dated 26-02-2019 Rs.20,000 Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	COLOMYCIN 2 million International Units (IU) of MHRA approved
	Me-too status	Coliject Injection. Of M/s GEOFMAN,(Reg # 035086)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator	• Stability studies required.

	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
203.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd.Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medforge 5/80/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 9806 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
204.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medforge 5/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 9805 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved.	
205.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medforge 5/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…160mg

		Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 9805 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved.	
206.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medforge 10/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 9807 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069550)
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved.	
207.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	SPA Med 40mg/2ml Injection
	Composition	Each 2ml contains: Drotaverine Hcl…40mg
	Diary No. Date of R& I & fee	Dy.No. 9704 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Three European countries Bulgaria**,** Romania**,** Hungary
	Me-too status	Hi-Spa 40mg/2ml Injection of M/s Helix
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
208.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Mexodine 30mg/5ml
	Composition	Each 5ml contains:

		Fexofenadine HCL…30mg
	Diary No. Date of R& I & fee	Dy.No. 9788 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA apprpoved
	Me-too status	Aloc 30mg/5ml Susp of M/s Bosch
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
209.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Merbinamed Tablet 135mg
	Composition	Each film coat Tablet Contains: Mebeverine Hcl…135mg
	Diary No. Date of R& I & fee	Dy.No. 9789 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anticholinergics
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	30's, 40's, 100's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mebeverine hydrochloride 135 mg of MHRA approved
	Me-too status	Mevos Tablets 135mg by M/s. Dyson Research Laboratories .
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
210.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefipod DS 100mg/5ml
	Composition	Each 5ml contains: Cefpodoxime Proxetil eq to Cefpodoxime ……100mg
	Diary No. Date of R& I & fee	Dy.No. 11245 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml,,, 100ml; ; As per PRC
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime proxetil 100mg / 5 ml powder for oral suspension of USFDA approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
211.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clinbez Gel
	Composition	Each gram of gel contains: Clindamycin phosphate eq to clindamycin…10mg (1% w/w) Hydrous benzoyl peroxide eq to anhydrous benzoyl peroxide …50mg (5 % w/w)
	Diary No. Date of R& I & fee	Dy.No. 11246 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019

	Pharmacological Group	Anti-Acne Preparations For Topical Use
	Type of Form	Form 5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10gm ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Duac Once Daily 10 mg/g + 50 mg/g Gel of MHRA approved
	Me-too status	Acnecib Gel of M/s Ciba Pharmaceuticals
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
212.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flozin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin IH…10MG
	Diary No. Date of R& I & fee	Dy.No. 11249 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antidiabetic (Sodium-glucose cotransporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE tablets (USFDA) approved
	Me-too status	Empa 10mg of M/s CCL pharmaceuticals
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
213.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flozin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin IH…25MG
	Diary No. Date of R& I & fee	Dy.No. 11250 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antidiabetic (Sodium-glucose cotransporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE tablets (USFDA) approved
	Me-too status	
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
214.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Emphomet Tablet 5/850mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy.No. 11260 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification

	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5 mg/850 mg of EMA approved
	Me-too status	
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
215.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Emphomet Tablet 5/1000mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No. 11261 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5 mg/1000 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
216.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Emphomet Tablet 12.5/500mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No. 11262 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 12.5 mg/500 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
217.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Emphomet Tablet 12.5/1000mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No. 11264 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification

	Pack size & Demanded Price	7's, 10's, 14's, 28's, 30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 12.5 mg/1000 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
218.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gentasone Cream
	Composition	Each gram of cream contains: Gentamicin sulphate eq to Gentamicin…1mg (0.1% w/w) Betamethasone valerate eq to Betamethasone…1mg (0.1% w/w)
	Diary No. Date of R& I & fee	Dy.No. 11251 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-bacterial and anti-inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10gm,20gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Valiosone G cream of Canada approved
	Me-too status	Valigent Cream of M/s Xenon Pharmaceuticals (Reg#029705)
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
219.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gentasone H Cream
	Composition	Each gram of cream contains: Gentamicin sulphate…1mg (0.1%W/W) Hydrocortisone acetate…10mg (1% W/W)
	Diary No. Date of R& I & fee	Dy.No. 11252 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-bacterial and anti-inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10gm, 15gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Genta-Hc Cream of M/s Epoch Pharmaceuticals (Reg # 030854)
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
220.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Alzem Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Mementine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 11241 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	7's, 10's, 20's, 30's, 56's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebixa 10 mg of MHRA Approved

	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
221.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Pirocam Gel 0.5%
	Composition	Each gram of gel contains: Piroxicam…5mg (0.5% w/w)
	Diary No. Date of R& I & fee	Dy.No. 11258 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	20gm, 25gm / As per SRO
	Approval status of product in Reference Regulatory Authorities	Feldene 0.5% w/w Gel. Of MHRA approved
	Me-too status	Pioxi Gel 0.5% of M/s Linta pharmaceuticals (Reg.# 080263)
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
222.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Biome Capsule 20/1100mg
	Composition	Each Capsule Contains: Sodium bicarbonate…20mg Omeprazole…1100mg
	Diary No. Date of R& I & fee	Dy.No. 11243 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Proton pump inhibitor + Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Zegerid Capsule by (USFDA Approved)
	Me-too status	Zoltar Insta 20mg Capsule of M/s Pharmevo
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
223.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals.Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Biome Capsule 40/1100mg
	Composition	Each Capsule Contains: Sodium bicarbonate…40mg Omeprazole…1100mg
	Diary No. Date of R& I & fee	Dy.No. 11244 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Proton pump inhibitor + Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	7's, 10's, 14's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Zegerid Capsule 40/1100mg by Santarus Inc (USFDA Approved)
	Me-too status	Faast Plus Capsule by CCL Pharma (Reg# 060325)
	GMP status	GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	

224.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Dron 70mg Tablet
	Composition	Each Tablet Contains: Alendronate Sodium Eq. to Alendronic Acid…70mg
	Diary No. Date of R& I & fee	Dy.No. 14400 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Bisphosphonate (Antiosteoporotic)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Alendronic Acid 70mg of MHRA approved
	Me-too status	Bonafide Tablets 70mg by M/s Medisure Labs.
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision:Deferred for consideration on its turn.	
225.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aricure 50mg/5ml IV Injection
	Composition	Each 5ml Ampoule Contains: Atracurium Besylate…50mg
	Diary No. Date of R& I & fee	Dy.No. 14328 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Non depolarizing muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tracrium Injection10mg/ml of MHRA approved
	Me-too status	Atrium Injections by M/s Searle Pakistan, Karachi (R#053342)
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision:Deferred for consideration on its turn.	
226.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aripine 1mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No. 14385 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Atropine Sulfate Injection 1mg in 1 ml of MHRA approved
	Me-too status	Swiss Atropine 1mg/ml Inj. of M/s Swiss Pharma (R#044290**)**
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
227.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Bamral 20mg Tablet
	Composition	Each Tablet Contains: Bambuterol Hcl…20mg
	Diary No. Date of R& I & fee	Dy.No. 14367 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Long acting beta adrenoceptor agonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bambec Tablet of (MHRA Approved)
	Me-too status	Long acting beta adrenoceptor agonist
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
228.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Clomix 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clomipramine HCl……75mg
	Diary No. Date of R& I & fee	Dy.No. 14402 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clomipramine HCl by sandoz ANSM france Approved
	Me-too status	Clomipril Tablets of M/s Libra Reg# 027816
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.

	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
229.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Desatil 2.5mg/5ml Syrup
	Composition	Each 5ml contains: Desloratadine…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 14360 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex of (USFDA approved)
	Me-too status	Desora Syrup by M/s S.J &G. Fazul Ellahie
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
230.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ibudex 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R& I & fee	Dy.No. 14395 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	NSIADs
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen of (MHRA approved)
	Me-too status	Bekonil 200mg Tablet of M/s Martin Dow
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
231.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Arinate 50mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Dimenhydrinate…50mg
	Diary No. Date of R& I & fee	Dy.No. 14374 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification

	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Dimenhydrinate Inj of Fresenius kabi, USFDA
	Me-too status	Dirinate Injection Each Ml Ampoule Contains:- Dime of M/s Elite Pharma
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
232.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Co-Besart 300/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 14380 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Angiotensin receptor blockers/diuretics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE of (USFDA approved)
	Me-too status	Irbest Plus Tablets of M/s Highnoon Laboratories
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
233.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ketalog 500mg/10ml Injection
	Composition	Each 10ml Ampoule Contains: Ketamine Hcl Eq. to Ketamine…500mg
	Diary No. Date of R& I & fee	Dy.No. 14392 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	General Anesthesic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketalar 50 mg/ml Injection, of MHRA approved 10ml
	Me-too status	Katafast 500mg Injection by M/s Vision
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities

		provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
234.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ketor 30mg/ml Injection
	Composition	Each 1ml ampoule contains: Ketorolac Tromethamine…30mg
	Diary No. Date of R& I & fee	Dy.No. 14394 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Toradol 30mg/ml of TGA approved
	Me-too status	Ketopan Injection 30mg by M/s Welwrd Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
235.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aricain 10mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Lidocaine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 14373 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Local anaesthetic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lidocaine Injection 1% w/v (MHRA approved)
	Me-too status	Lacain 1% Injection of M/s. Pulse Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	Firm has mentioned " Each 1ml ampoule in some parts of form 5 and at the same time also mentioned filled volume 2ml. Firm has clarified the volume as 2ml, however revised form 5, applicable fee not submitted.
	Decision: Deferred for consideration on its turn.	
236.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Co-Locor 50/12.5 mg Tablet

	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 14359 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist,Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar Comp 50 mg/12.5 mg of (MHRA Approved)
	Me-too status	Lotass Plus 50mg/12.5mg of M/S Getz pharma
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
237.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Prox 37.5mg CR Tablet
	Composition	Each Enteric Film Coated Controlled Release Tablet Contains: Paroxetine Hcl Eq. to Paroxetine…37.5mg
	Diary No. Date of R& I & fee	Dy.No. 14357 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Paraxyl CR M/s CCL Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	.
	Decision: Deferred for consideration on its turn.	
238.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Arixicam IM 20mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Piroxicam…20mg
	Diary No. Date of R& I & fee	Dy.No. 14393 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form -5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France

	Me-too status	Salden 20mg Injection of M/s Danas Pharma (Reg.#080373)
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	.
	Decision: Deferred for consideration on its turn.	
239.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Thioside 4mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy.No. 14382 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis ANSM France
	Me-too status	Myovi 4mg/2ml Injection by Macter Intl.(Reg. No. 058692)
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator [IV]	.
	Decision:Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
240.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin Met Tablets 5/850mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy.No. 9794 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's,14's, 28's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5 mg/1000 mg of EMA approved
	Me-too status	
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	

241.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin Met Tablets 5/1000mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No. 9790 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's,14's, 28's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5 mg/1000 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
242.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin Met Tablets 12.5/500mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No. 9792 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's,14's, 28's, 30's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 12.5 mg/500 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
243.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin Met Tablets 12.5/850mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy.No. 9793 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's,14's, 28's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 12.5 mg/850 mg of EMA approved
	Me-too status	

	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
244.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin Met Tablets 12.5/1000mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No. 9791 dated 04-03-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's,14's, 28's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 12.5 mg/1000 mg by Boehringer Ingelheim Pharmaceuticals, USFDA
	Me-too status	
	GMP status	Last GMP inspection conducted on 02-04-2019, and report concludes firm was considered to be operating at an acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator [IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
245.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited.149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Fedpro 40mg Tablets
	Composition	Each enteric coated tablet contains: Pantaprazole as Sodium sesquihydrate …40mg
	Diary No. Date of R& I & fee	Dy.No 4918 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg Tablet Of (MHRA Approved)
	Me-too status	Pantopraz 40mg Tablet M/s Klifton Pharma,
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance
	Remarks of the Evaluator	The firm change formulation from while in applied formulation Pantotprazole to Pantotprazole as sodium sesquihydrate with submission of fee of Rs: 5000/- Deposit slip no# 0738748, Dated: 22-07-2020
	Decision: Approved.	
246.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited.149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Respedone 3mg Tablets
	Composition	Each Film Coated Tablet Contains: Risperidone…3mg
	Diary No. Date of R& I & fee	Dy.No 7992 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019

	Pharmacological Group	Sedative
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ,12'2, 18's, 20's, 30's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 3mg of (MHRA approved)
	Me-too status	Rislet 3mg Tablet M/s. High-Q Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance
	Remarks of the Evaluator	
	Decision: Approved.	
247.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited.149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Respedone 4g Tablets
	Composition	Each Film Coated Tablet Contains: Risperidone…4mg
	Diary No. Date of R& I & fee	Dy.No 7993 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Sedative
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ,12'2, 18's, 20's, 30's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 4mg of (MHRA approved)
	Me-too status	Rislet 4mg Tablet M/s. High-Q Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance
	Remarks of the Evaluator	
	Decision: Approved.	
248.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited.149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Tizafed 2mg Tablets
	Composition	Each Tablet Contains: Tizanidine as HCL…2mg
	Diary No. Date of R& I & fee	Dy.No 4927 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 2mg Tablet M/s High-Q Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance

	Remarks of the Evaluator	• The firm change formulation from film coated to uncoated tablet with submission of fee of Rs: 5000/- Deposit slip no# 0081716, Dated: 22-07-2020
	Decision: Approved.	
249.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited.149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Tizafed 4mg Tablets
	Composition	Each Tablet Contains: Tizanidine as HCL…4mg
	Diary No. Date of R& I & fee	Dy.No 4917 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 4mg Tablet M/s High-Q Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance
	Remarks of the Evaluator	• The firm change formulation from film coated to uncoated tablet with submission of fee of Rs: 5000/- Deposit slip no# 0559544, Dated: 22-07-2020
	Decision: Approved.	
250.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Lahore Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Qutin XR 100mg Tablet
	Composition	Each extended release tablet contains: Quetiapine as fumarate eq to Quetiapine…100mg
	Diary No. Date of R& I & fee	Dy.No 9208 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	

251.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd.23km, Raiwind Road, Lahore By: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Apex 40mg Injection
	Composition	Each Vial Contains: Omeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Dy.No 8292 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazol 40mg injection of (MHRA approved)
	Me-too status	Fymezole Dry Powder Injection IV of M/s Fynk Pharma
	GMP status	Last GMP inspection of GT Pharma conducted on 31-01-2019 and the report concludes that the firm was found to be GMP compliant & Certificate of GMP Issued on 16-01-2018.
	Remarks of the Evaluator	• Copy of Contract manufacturing agreement attached • Number of sections of applicant approved by Licensing Board : 04 • Number of products already registered/approved on contract manufacturing in the name of applicant : Nil
	Decision: Approved with innovator's specification.	
252.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd.23km, Raiwind Road, Lahore By M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Spell 40mg Injection
	Composition	Each Vial Contains: Esomeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Dy.No 8293 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV injection of (USFDA approved)
	Me-too status	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last GMP inspection of GT Pharma conducted on 31-01-2019 and the report concludes that the firm was found to be GMP compliant & Certificate of GMP Issued on 16-01-2018.
	Remarks of the Evaluator	• Copy of Contract manufacturing agreement attached • Number of sections of applicant approved by Licensing Board : 04 • Number of products already registered/approved on contract manufacturing in the name of applicant : Nil
	Decision: Approved with innovator's specification.	
253.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Forbec 100/6 mcg Inhaler
	Composition	Each Metered Dose Contains: Beclomethasone Dipropionate…100mcg Formoterol Fumarate…6mcg
	Diary No. Date of R& I & fee	Dy.No. 10522 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Adrenergic in comination with corticosteriod

	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	120 actuation: As per SRO
	Approval status of product in Reference Regulatory Authorities	Fostair 100/6 micrograms per actuation pressurised inhalation solution of MHRA approved
	Me-too status	Foster Pressurized Metered Dose Inhaler. By Chiesi pharmaceutica
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	• Complete details of container.closure system/device required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.** • **Complete details of container closure system/device.**	
254.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Edoban 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Edoxaban Tosilate Eq. to Edoxaban…15mg
	Diary No. Date of R& I & fee	Dy.No. 13933 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Antithrombotic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Lixiana 15 mg film-coated tablets of MHRA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.
	Decision: Deferred for consideration on its turn.	
255.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Ercaf 1/100 mg Tablet
	Composition	Each Film Coated Tablet Contains: Ergotamine Tartrate…1mg Caffeine…100mg
	Diary No. Date of R& I & fee	Dy.No. 13936 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Ergot Alkaloid/ Xanthine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cafergot of USFDA approved
	Me-too status	Cafergot TAB of M/s SANDOZ
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

256.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Fidox 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Fidaxomicin…200mg
	Diary No. Date of R& I & fee	Dy.No. 13931 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's,c 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	DIFICLIR 200 mg film-coated tablets of MHRA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit stability studies along with requisite documents
	Decision: Deferred for consideration on its turn.	
257.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Talim 0.5mg Capsule
	Composition	Each Capsule Contains: Tacrolimus…0.5mg
	Diary No. Date of R& I & fee	Dy.No. 9894 dated 04-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Immunosuppresant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Prograf of USFDA approved
	Me-too status	Inograf 0.5 mg capsule by Platinum Pharma (Reg.# 045490)
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
258.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Verlin 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Varenicline Tartrate Eq. to Varenicline…1mg
	Diary No. Date of R& I & fee	Dy.No. 13730 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Nicotinic acetylcholine receptor partial agonist/smoking cessation aid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Prograf of USFDA approved
	Me-too status	Chantix 1.0mg Of M/S Parke Davis & Co. (Reg.# 045698)
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

259.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Riocig 0.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Riociguat…0.5mg
	Diary No. Date of R& I & fee	Dy.No. 13725 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Anti hypertensive
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	30's, 60's, :As per SRO
	Approval status of product in Reference Regulatory Authorities	Adempas of USFDA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.
	Decision: Deferred for consideration on its turn.	
260.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Pirnix 534 mg Tablet
	Composition	Each Film Coated Tablet Contains: Pirfenidone…534mg
	Diary No. Date of R& I & fee	Dy.No. 13963 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Anti-fibrotic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	7's, 14, 21;s :As per SRO
	Approval status of product in Reference Regulatory Authorities	Esbriet 534 mg film-coated tablets of MHRA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.
	Decision: Deferred for consideration on its turn.	
261.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Indap 10/1.25/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Perindopril Argenine……10mg Indapamide……..1.25mg Amlodipine as Besylate……10mg
	Diary No. Date of R& I & fee	Dy.No. 9890 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30, 60;s :As per SRO
	Approval status of product in Reference Regulatory Authorities	Coverdine 5mg/1.25mg/10mg film-coated tablets of HPRA Ireland approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.

	Decision: Deferred for submission of stability study data as per requirements of 293rd meeting of Registration Board.	
262.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Obecol 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid…10mg
	Diary No. Date of R& I & fee	Dy.No. 13928 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Bile acid prepartions
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20, 30;s :As per SRO
	Approval status of product in Reference Regulatory Authorities	OCALIVA 5 mg film-coated tablets of MHRA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator IV	Submit Stability studies along with requisite documents.
	Decision: Deferred for consideration on its turn.	
263.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Morphate 100mg/5ml Oral Syrup
	Composition	Each 5ml Contains: Morphine Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No. 10510 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019
	Pharmacological Group	Opoid analgesic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	15ml, 30ml, 60ml, 90ml, 120ml:As per SRO
	Approval status of product in Reference Regulatory Authorities	Morphine Sulfate Oral Solution of USFDA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator IV	Submit Stability studies along with requisite documents.
	Decision: Deferred for following: • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.** • **Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
264.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Baclan 10mg Tablet
	Composition	Each Tablet Contains: Baclofen…….10mg
	Diary No. Date of R& I & fee	Dy.No. 10657 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Muscle Relaxant and antispastic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's, 3x 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen of (MHRA approved)
	Me-too status	Baclin Tablets Of M/S Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.

	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553518 Dated : 28-07-2020
	Decision: Approved.	
265.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Cinitax 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride as acid tartrate.…1mg
	Diary No. Date of R& I & fee	Dy.No. 10665 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1 mg Tablet of Spain approved
	Me-too status	Cint 1mg Tablet M/s High-Q Pharmaceutical
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553519 Dated : 28-07-2020
	Decision: Approved with innovator's specification.	
266.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Eper 50mg Tablet
	Composition	Each Sugar coated Tablet Contains: Eperisone HCl……50mg
	Diary No. Date of R& I & fee	Dy.No. 10656 dated 05-03-2019 Rs.20,000/- Dated 5-03-2019
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, 2 x 10's, 3 x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Myonal 50mg Tablet of PMDA Approved
	Me-too status	Berelax 50mg Tablet by Ray Pharma Karachi Reg# 061084
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to Sugar coated tablet with submission of fee of RS: 5000/- .Deposit slip no # 0553520 Dated : 28-07-2020
	Decision: Approved with innovator's specification.	
267.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Ivertin 6mg Tablet
	Composition	Each film coatedTablet Contains: Ivermectin…….6mg
	Diary No. Date of R& I & fee	Dy.No. 10666 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Semisynthetic anthelmintic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, 2 x10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	I-Mec Tablets t of M/s Alen Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-08-2018 and report that panel recommend grant of

		GMP certificate.
	Remarks of the Evaluator [IV]	• Stromectol 6mg (Uncoated) of USFDA Discontinued (submitted by firm) • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
268.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Eperol 25mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…25mg
	Diary No. Date of R& I & fee	Dy.No. 10648 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMICTAL 25mg Tablets (USFDA approved)
	Me-too status	Epictal 25mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoaed tablet with submission of fee of RS: 5000/- Deposit slip no # 0553521 Dated : 28-07-2020
	Decision: Approved.	
269.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Eperol 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…50mg
	Diary No. Date of R& I & fee	Dy.No. 10650 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamictal 50mg (MHRA approved)
	Me-too status	Epictal 50mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553522 Dated : 28-07-2020
	Decision: Approved.	
270.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Eperol 100mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…100mg
	Diary No. Date of R& I & fee	Dy.No. 10649 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	20's, 30's: As per SRO

	Approval status of product in Reference Regulatory Authorities	Lamictal 100mg (MHRA approved)
	Me-too status	Epictal 100mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553523 Dated : 28-07-2020
	Decision: Approved.	
271.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Zolin 600mg Tablet
	Composition	Each film coated Tablet Contains: Linezolid…….600mg
	Diary No. Date of R& I & fee	Dy.No. 10654 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Oxazoldone Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	2 x 6's ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Ecasil 600mg tablet by M/s Sami (Reg#066904)
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from enteric coated tablet to Film coated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553524 Dated : 28-07-2020
	Decision: Approved with innovator's specification.	
272.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Artist 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan……..20mg
	Diary No. Date of R& I & fee	Dy.No. 10651 dated 05-03-2019 Rs.20,000/- Dated05-03-2019
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's, 2 x 10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 20mg Tab by Highnoon Laboratories (Reg #065686)
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	Firm change formulation from film coated tablet to uncoated tablet with submission of fee of RS: 5000/- Deposit slip no # 0553525 Dated : 28-07-2020
	Decision: Approved.	
273.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Klovir 800mg Tablet
	Composition	Each Tablet Contains: Acyclovir ……800mg
	Diary No. Date of R& I & fee	Dy.No. 12686 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 25's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Aciclovir 800 mg Tablets of MHRA approved
	Me-too status	Virocyc Tablets of M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
274.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zovir 250mg/10ml Injection
	Composition	Each 10ml Vial Contains: Acyclovir…250mg
	Diary No. Date of R& I & fee	Dy.No. 14299 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's (10ml); As per SRO
	Approval status of product in Reference Regulatory Authorities	Zovirax I.V. 250 mg of MHRA approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for consideration on its turn.	
275.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zovir 500mg/10ml Injection
	Composition	Each 20ml Contains: Acyclovir…500mg
	Diary No. Date of R& I & fee	Dy.No. 14298 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's (20ml) ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zovirax I.V. 500 mg of MHRA approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for consideration on its turn.	
276.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Beta One Lotion 0.1%
	Composition	Each ml contains: Betamethasone valerate…0.1% w/w

	Diary No. Date of R& I & fee	Dy.No. 17417 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Betnovate Lotion 0.1% w/w by (MHRA Approved
	Me-too status	Betamethasone Lotion by M/s Werrick Pharmaceuticals, (Reg# 051176)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
277.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bosnim 62.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bosentan Monohydrate Eq. to Bosentan ……62.5mg
	Diary No. Date of R& I & fee	Dy.No. 12691 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Endothelin Receptor Antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tracleer of USFDA approved
	Me-too status	Bozpah 62.5mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
278.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clintek Gel
	Composition	Each Gm Contains: Clindamycin Phosphate…12mg (1.2 % w/w) Tretinoin…0.25mg (0.025% w/w)
	Diary No. Date of R& I & fee	Dy.No. 14070 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-Acne (Treatment of acne vulgaris)
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20gm ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZIANA (Gel) of USFDA approved
	Me-too status	Clin Gel 20g Gel of M/s Linta pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

279.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Donil 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil Hcl…5mg
	Diary No. Date of R& I & fee	Dy.No. 12722 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anticholinesterases
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Donepezil Hydrochloride 5 mg film-coated tablets of MHRA Approved
	Me-too status	Remembrin Tablets by PharmEvo (Reg. No#045401)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
280.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Donil 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 12718 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anticholinesterases
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Donepezil Hydrochloride 10 mg film-coated tablets of MHRA Approved
	Me-too status	Remembrin Tablets by PharmEvo (Reg. No# 045402)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
281.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Uric Tablet 120mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…120mg
	Diary No. Date of R& I & fee	Dy.No. 17443 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antigout preparation (Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ADENURIC 120 mg film-coated tablets of MHRA approved
	Me-too status	Gouric 120mg Tablet of M/s Pharmevo (Reg #080284)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

282.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Filget 300mcg Injection
	Composition	Each Vial Contains: Filgrastim…300mcg
	Diary No. Date of R& I & fee	Dy.No. 14258 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Rcombinent G-CSf
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1's, 5's:/ As per SRO
	Approval status of product in Reference Regulatory Authorities	NEUPOGEN 30 MU (0,3 mg/mL), solution injectable **of** ANSM france approved **(Available in prefilled syringes)**
	Me-too status	GRASTIN INJECTION of M/s CCl (Reg # 052246)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Registration board referred the case to Biological Division since applied formulation is of rDNA origin.	
283.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Arbex 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…….150mg
	Diary No. Date of R& I & fee	Dy.No. 12670 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Angiotensin-II receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aprovel 150 mg film-coated tablets of (MHRA approved)
	Me-too status	Irbest Tablets 150mg of M/s. Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
284.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Arbex 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…….300mg
	Diary No. Date of R& I & fee	Dy.No. 12715 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Angiotensin-II receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aprovel 300 mg film-coated tablets of (MHRA approved)
	Me-too status	Irbest Tablets 300mg of M/s. Highnoon Laboratories,

	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
285.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Arbex D 300/12.5 mg Tablet
	Composition	Each Film Caoted Tablet Contains: Irbesartan…300mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 12716 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Angiotensin receptor blockers/diuretics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE of (USFDA approved)
	Me-too status	Irbest Plus Tablets of M/s Highnoon Laboratories
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
286.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Irofit Tablet 20mg/2.5mg
	Composition	Each Film Coated Tablet Contains: Iron protein succinylate 400mg eq to elemental iron …20mg Folic Acid……..2.5mg
	Diary No. Date of R& I & fee	Dy.No. 17427 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antianemic preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 14's, 20's , :As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Eisen Tablets of Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting
	Decision: Deferred for consideration on its turn.	
287.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ornex 3g Sachet
	Composition	Each Sachet Contains: L-Ornithine-L-Aspartate…3gm
	Diary No. Date of R& I & fee	Dy.No. 12707 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Hepatoprotectant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Hepa-Merz Sachet containing ornithine aspartate (granules for solution). AGES approved
	Me-too status	Couthy 3gm Sachet of M/s Martin Dow
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	Refrence product contains granules while applied product contain powder. Now firm change form 5 and formulation with granules.
	Decision: Deferred for consideration on its turn.	
288.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fenak 500mg Tablet
	Composition	Each film coated Tablet Contains: Mefenamic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No. 12702 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	100's, 200's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ponstan Forte Tablets 500mg of MHRA approved
	Me-too status	Genston 500mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	• The firm change formulation from uncoated to film coated with submission of fee of RS: 5000/- Deposit slip no # 2017949, Dated: 03-08-2020
	Decision: Deferred for consideration on its turn.	
289.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Methane 1% w/v Lotion
	Composition	Each ml Contains: Permethrin…10mg
	Diary No. Date of R& I & fee	Dy.No. 14296 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Pyrethroid insecticide
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	30ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Nix lotion of USFDA approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for consideration on its turn.	
290.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Proman 10mg/ml Injection

	Composition	Each ml contains: Protamine sulphate…10mg
	Diary No. Date of R& I & fee	Dy.No. 14263 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antidote to heparin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml x 1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Protamine Sulfate 10mg/ml Solution for Injection of MHRA approved
	Me-too status	Protamine Sulphate Injection of M/s Isman Drugs House Lahore. (Reg.# 008853)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	Source: Biological
	Decision: Deferred for consideration on its turn.	
291.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rancol xr 1000mg
	Composition	Each film coated extended release tablet contains: Ranolazine…1000mg
	Diary No. Date of R& I & fee	Dy.No. 17435 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti-Anginal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	14's :As per SRO
	Approval status of product in Reference Regulatory Authorities	RANEXA of USFDA Approved
	Me-too status	Ranoline SR 1000mg Tablet (Reg# 078790) by Searle IV Solutions
	GMP status	Last GMP inspection conducted on 19 -09-2018 aAnd report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated s Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
292.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rivarox 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy.No. 12725 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	14's, : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 15mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 15mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	

293.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rovi 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium Salt…5mg
	Diary No. Date of R& I & fee	Dy.No. 12698 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	HMG CoA reductase inhibitor/Antihyprlipidemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	CRESTOR tablet of (USFDA approved)
	Me-too status	RosuBar 5mg Tablet by M/s Barrett Hodgson
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
294.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Silrex 1% Cream
	Composition	Each Gram Contains: Sulpher Sulphadiazine…10mg
	Diary No. Date of R& I & fee	Dy.No. 12708 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antibiotic for topical use
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10gm, 15gm, 20gm, 25gm, 30gm,50gm, 250gm, 500gm,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Silvadene Cream of (USFDA approved)
	Me-too status	Quench cream of M/s Ferozesons
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator [IV]	
	Decision: Deferred for consideration on its turn.	
295.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aricure 30mg/3ml Injection
	Composition	Each 3ml Ampoule Contains: Atracurium Besylate…30mg
	Diary No. Date of R& I & fee	Dy.No. 14387 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Non-depolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities

		provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Firm provided Atracurium 10mg/ml Solution for Injection or Infusion of MHRA approved. But 3ml volume not available in MHRA
	Decision: Deferred for consideration on its turn.	
296.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Bamral 5mg/5ml Syrup
	Composition	Each 5ml Contains: Bambuterol Hcl…5mg
	Diary No. Date of R& I & fee	Dy.No. 14370 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Btno 5mg/5ml syrup by M/s Genix (Reg# 057873)
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Firm provided Bambuterol juice 1mg/ml by AstraZaneca (Germany) but in Germany only 1mg mentioned ml not mentioned
	Decision: Deferred for consideration on its turn.	
297.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Dobicard 250mg/5ml IV Injection
	Composition	Each 5ml Ampoule Contains: Dobutamine Hcl…250mg
	Diary No. Date of R& I & fee	Dy.No. 14391 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	General anesthetic
	Type of Form	Form-5
	Finished product Specifications	USP Specs.
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Botamin Injection by M/s Fynk Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation

		and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	Firm submitted fee of Rs: 5000/- Deposit slip No# 1984287,Dated: and Revise formulation as follows Dobicard 250mg/20ml IV Injection Each 20ml Contains: Dobutamine Hcl…250mg Dobutrex dobutamine 250mg/20ml injection solution of TGA approved Dobutamine Injection 250mg/20ml of Haji medicine (Reg # 027345)
	Decision: Deferred for consideration on its turn.	
298.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levon 1.5mg Tablet
	Composition	Each Tablet Contains: Levonorgestrel…1.5mg
	Diary No. Date of R& I & fee	Dy.No. 14365 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Hormonal contraceptives for systemic use
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	1 x 10's , 1 x 20's, 1 x 30's:as per SRO
	Approval status of product in Reference Regulatory Authorities	Ezinelle 1.5 mg tablet of MHRA approved
	Me-too status	Emkit-DS tablet 1.5mg of Zafa Pharma Reg # 032543.
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	• The firm change formulation from film coated to un coated with submission of fee of Rs: 5000/- Deposit slip No # 1984286, Dated : 07-08-2020. • Approval of section/manufacturing facility (Steriodal hormonal tablet) by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for consideration on its turn.	
299.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Mebofac MR 200mg Capsule
	Composition	Each Capsule Contains: Enteric Coated Pellets Mebeverie Hcl 50% Eq. to Mebeverie Hcl…200mg
	Diary No. Date of R& I & fee	Dy.No. 14372 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	10's, 30's & 40's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Mebever MR capsule of M/s Getz Pakistan (050747)
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on

		cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	Source of pellets : Vision pharmaceuticals
	Decision: Deferred for consideration on its turn.	
300.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Averon 4mg Tablet
	Composition	Each film coated Tablet Contains: Ondansetron Hcl Dihydrate Eq. to Ondansetron…….4mg
	Diary No. Date of R& I & fee	Dy.No. 14389 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's,50's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN Of (USFDA Approved)
	Me-too status	Ondonix 4mg Tablet M/s Genix Pharma
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm
	Remarks of the Evaluator [IV]	• The firm change formulation from uncoated to film coated with submission of feeof Rs: 5000/- Deposit slip No # 1984285, Dated : 07-08-2020
	Decision: Deferred for consideration on its turn.	
301.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Ilazole 10mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Ilaprazole……10mg
	Diary No. Date of R& I & fee	Dy.No. 13960 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for consideration on its turn.	

302.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Ilazole 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Ilaprazole……20mg
	Diary No. Date of R& I & fee	Dy.No. 13961 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for consideration on its turn.	
303.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Ranol ER 375mg Tablet
	Composition	Each film coated Extended Release Tablet Contains: Ranolazine…375mg
	Diary No. Date of R& I & fee	Dy.No. 10001 dated 04-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Anti-Anginal
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 20's, 30's, 60's, 100's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranexa 375 mg prolonged-release tablets of TGA (Australia) Approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
304.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Ranol ER 750mg Tablet
	Composition	Each film coated Extended Release Tablet Contains: Ranolazine…750mg
	Diary No. Date of R& I & fee	Dy.No. 10002 dated 04-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Anti-Anginal
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 20's, 30's, 60's, 100's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranexa 750 mg prolonged-release tablets of TGA (Australia) Approved
	Me-too status	Not found

	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Submit Stability studies along with requisite documents.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
305.	**Duplication at serial no. 304.**	
306.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Lorgy d 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…….5mg
	Diary No. Date of R& I & fee	Dy.No. 10659 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	CLARINEX of USFDA approved
	Me-too status	Larinex Tablets of M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
307.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals Pvt Ltd 112-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Lorgy-D 0.5mg/ml Syrup
	Composition	Each ml contains: Desloratadine…0.5mg
	Diary No. Date of R& I & fee	Dy.No. 10660 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	60 ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex of (USFDA approved)
	Me-too status	Desora Syrup by M/s S.J &G. Fazul Ellahie
	GMP status	Last GMP inspection conducted on 30-08-2018 and report concludes that panel recommend grant of GMP certificate.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
308.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Accel 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy.No. 11430 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac of (MHRA approved)
	Me-too status	Acfonac 100mg Tablets M/s Medicraft
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."

	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
309.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bambu 10mg Tablet
	Composition	Each Tablet Contains: Bambuterol Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 11431 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Long acting beta adrenoceptor agonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Bambec Tablet of (MHRA Approved)
	Me-too status	Bambu 10mg Tablets of M/s Alliance Pharmaceuticals
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
310.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bambu 20mg Tablet
	Composition	Each Tablet Contains: Bambuterol Hcl…20mg
	Diary No. Date of R& I & fee	Dy.No. 11436 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Long acting beta adrenoceptor agonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Bambec Tablet of (MHRA Approved)
	Me-too status	Bambu 20mg Tablets of M/s Alliance Pharmaceuticals
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
311.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Esone 50mg Tablet
	Composition	Each film coated Tablet Contains: Eperisone HCl …50mg
	Diary No. Date of R& I & fee	Dy.No. 11420 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 20's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authoritiesf	Expose 50mg Tablet of AIFA Italy approved
	Me-too status	Berelax 50mg Tablet by Ray Pharma Karachi Reg#061084
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	Firm change formulation from un coated tablet to film coated tablet with submission of fee of RS: 5000/- Deposit slip no # 1996273 Dated : 10-08-2020
	Decision: Approved with innovator's specification.	

312.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Febsta 40mg Tablet
	Composition	Each film coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R& I & fee	Dy.No. 11427 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	5's, 10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40mg Tablet of (USFDA approved)
	Me-too status	Febuxin 40mg Tablet of M/s AGP
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	Firm change formulation from un coated tablet to film coated tablet with submission of fee of RS: 5000/- Deposit slip no # 1996274 Dated : 10-08-2020
	Decision: Approved with innovator's specification.	
313.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Febsta 80mg Tablet
	Composition	Each film coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Dy.No. 11435 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 80mg Tablet of (USFDA approved)
	Me-too status	Febuxin 80mg Tablet of M/s AGP
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	Firm change formulation from un coated tablet to film coated tablet with submission of fee of RS: 5000/- Deposit slip no # 1996275 Dated : 10-08-2020
	Decision: Approved with innovator's specification.	
314.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zulid 100mg Suspension
	Composition	Each 5ml contains: Linezolid…100mg
	Diary No. Date of R& I & fee	Dy.No. 11432 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specification
	Pack size & Demanded Price	30ml, 60 ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 100 mg/5ml Granules For Oral Suspension By M/S Pharmacia Limited, (USFDA)
	Me-too status	Linzol 100mg /5ml oral dry suspension of M/s Regal Pharma
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	

315.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Locam 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy.No. 11428 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of M/s AGP
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
316.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Sopro 200mcg Tablet
	Composition	Each Tablet Contains: Misoprostol as 1 % HPMC…200mcg
	Diary No. Date of R& I & fee	Dy.No. 11429 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Prostaglandin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, 20's,30's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec of (FDA approved)
	Me-too status	Miso 200mcg tablet M/s Global Pharmaceuticals,
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
317.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nalphine 10mg Injection
	Composition	Each ml contains: Nalbuphine as Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 11423 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nubain Injection 10mg/ml of Health Canada approved
	Me-too status	Nalfy Injection 10mg by M/s. Vision Pharmaceuticals,
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	Terminal sterilization not performed.
	Decision:Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization.	
318.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nalphine 20mg Injection
	Composition	Each ml contains: Nalbuphine as Hcl…20mg

	Diary No. Date of R& I & fee	Dy.No. 11422 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nubain Injection 20mg/ml of Health Canada approved
	Me-too status	Nalfy Injection 20mg by M/s. Vision Pharmaceuticals,
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	Terminal sterilization not performed.
	Decision:Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization.	
319.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ptonix 40mg Tablet
	Composition	Each gastro resistant tabket contains: Pantoprazole as sodium sesquihydrate…40mg
	Diary No. Date of R& I & fee	Dy.No. 11426 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	7's, 14's,28's, , ; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg Tablet Of (MHRA Approved)
	Me-too status	Pantopraz 40mg Tablet M/s Klifton Pharma,
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
320.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Rocyl 5mg Tablet
	Composition	Each Tablet Contains: Procyclidine Hcl…5mg
	Diary No. Date of R& I & fee	Dy.No. 11434 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti-Parkinson Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's,30's, , ; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Kemadrin of USFDA approved
	Me-too status	Proclidine Tablets of M/ Shaheen Pharmaceuticals,
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator [IV]	
	Decision: Approved.	
321.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colchi 4mg Injection
	Composition	Each 2ml contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy.No. 11433 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	2ml x 6's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis ANSM France
	Me-too status	Myovi 4mg/2ml Injection by Macter International (058692)
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator IV	Terminal sterilization not performed.
	Decision: Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization.	
322.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tdol Plus Tablets 37.5mg/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol Hcl…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy.No. 11421 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharmaceuticals
	GMP status	Inspection conducted on 18-10-2018 and GMP compliance level is rated as GOOD."
	Remarks of the Evaluator IV	
	Decision: Approved.	
323.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name +Dosage Form + Strength	Cefmark 250mg/Vial I.M Dry Powd
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No. 17159 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin I.M injection of (MHRA approved)
	Me-too status	Accucef 250 mg IM Injection M/s Wel Wink Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator IV	
	Decision: Deferred for consideration on its turn.	
324.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name +Dosage Form + Strength	Cefmark 500mg/Vial I.M Dry Powd
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Diary No. Date of R& I & fee	Dy.No. 17154 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin I.M injection of (MHRA approved)

	Me-too status	Wixone 500 mg Injection IM M/s Wise Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator IV	
	Decision: Deferred for consideration on its turn.	
325.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name +Dosage Form + Strength	Cefmark 1gm/Vial I.M Dry Powd
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1gm
	Diary No. Date of R& I & fee	Dy.No. 17179 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin I.M injection of (MHRA approved)
	Me-too status	Accucef 1gm IM Injection M/s Wel Wink Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator IV	
	Decision: Deferred for consideration on its turn.	
326.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name +Dosage Form + Strength	Medifik 2% Cream
	Composition	Each Gram Contains: Fusidic Acid…20mg
	Diary No. Date of R& I & fee	Dy.No. 17165 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5gm, 15gm /As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin of MHRA Approved
	Me-too status	Ucid 2% Cream by Ciba Pharma (Reg. No. 081566)
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator IV	• Availability of Cream sections could not be confirmed.
	Decision: Deferred for consideration on its turn.	
327.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name +Dosage Form + Strength	Megenta Drops 0.3%
	Composition	Each 5ml contains: Gentamycin as sulphate…0.3% w/v
	Diary No. Date of R& I & fee	Dy.No. 12247 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Aminoglycoside Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5ml, 7.5ml & 10ml; /As per SRO
	Approval status of product in Reference Regulatory Authorities	Genoptic of USFDA approved
	Me-too status	Ocugent 0.3% 5ml & 10ml Drops of M/s Farmigea Pharma

	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML.
	Remarks of the Evaluator [IV]	Eye and Ear drop section available
	Decision: Deferred for consideration on its turn.	
328.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bex para 1000mg/100ml Injection
	Composition	Each 100ml contains: Paracetamol…1000mg
	Diary No. Date of R& I & fee	Dy.No. 41929 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	100ml ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Acetaminophen of (USFDA approved)
	Me-too status	Bofalgan 1g/100ml Infusion M/s Bosch Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
329.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Baxmeco 500mcg Injection
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No. 41928 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Co-enzyme-type vitamin B12
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved
	Me-too status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical,
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. &

		Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
330.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bex D3 Injection
	Composition	Each ml contains: Cholecalciferol…5mg
	Diary No. Date of R& I & fee	Dy.No. 41922 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
331.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexsucrose 100mg/5ml Injection
	Composition	Each 5ml contains: Iron Sucrose…100mg
	Diary No. Date of R& I & fee	Dy.No. 41930 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Iron replacement product
	Type of Form	Form 5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer 100mg/5ml Injection of MHRA approved
	Me-too status	Bisleri 100mg/5ml Injection of M/S Sami Pharma
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
332.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexdrota 40mg/2ml
	Composition	Each 2ml contains: Drotaverine HCL…40mg Drotaverine
	Diary No. Date of R& I & fee	Dy.No. 41926 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2ml x 25's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Three European countries Bulgaria, Romania, Hungary
	Me-too status	Hi-Spa 40mg/2ml Injection of M/s Helix
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	

333.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexome 40mg Injection
	Composition	Each vial of dry substance contains: Omeprazole Sodium eq to Omeprazole Sodium…40mg
	Diary No. Date of R& I & fee	Dy.No. 41923 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazol 40mg injection of (MHRA approved)
	Me-too status	Fymezole Dry Powder Injection IV of M/s Fynk Pharma
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
334.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Baxeso 40mg Injection
	Composition	Each vial of dry substance contains: Esomeprazole Sodium eq to Esomeprazole Sodium…40mg
	Diary No. Date of R& I & fee	Dy.No. 41927 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV injection of (USFDA approved)
	Me-too status	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view

		their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
335.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexsunate 30mg Injection
	Composition	Each vial of dry substance contains: Artesunate…30mg
	Diary No. Date of R& I & fee	Dy.No. 41919 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Gen-M Injection of M/s Genix Pharma
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
336.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexsunate 60mg Injection
	Composition	Each vial of dry substance contains: Artesunate…60mg
	Diary No. Date of R& I & fee	Dy.No. 41920 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma (Reg#057719)

	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
337.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bexsunate 120mg Injection
	Composition	Each vial of dry substance contains: Artesunate…120mg
	Diary No. Date of R& I & fee	Dy.No. 41921 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Gen-M Injection of M/s Genix Pharma
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
338.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Baxarit 80mg/ml Injection
	Composition	Each ml contains:

		Artemether…80mg
	Diary No. Date of R& I & fee	Dy.No. 41925 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved formulation
	Me-too status	Artesinate Injection of M/S Gray's Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
339.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals., A-1/A, Scheem No.33, Phase-1,S.I.T.E,Super Highway, Karachi Contract manufactured By: M/s Safe Pharmaceuticals Pvt Ltd., Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Baxtidine 50mg/ml Injecion
	Composition	Each 2ml contains: Ranitidine as Hydrochloride…50mg
	Diary No. Date of R& I & fee	Dy.No. 41924 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Antihistamine (H2 receptor antagonist)
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZANTAC Injection of USFDA approved
	Me-too status	Peptinil 50mg Injection of M/S Wilson's Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 20-09-2019, and the report concludes that the current compliance level of firm is rated as satisfactory. & Last inspection of Safe pharmaceuticals conducted on 04-03-2019 and report concludes that "All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good."
	Remarks of the Evaluator	Number of sections of applicant approved by Licensing Board: 08 Number of products already registered/approved on contract manufacturing in the name of applicant: Nil

	Decision: Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.	
340.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Volden-M 50mg/200mcg Tablet
	Composition	Each Delayed Release Tablet Contains: Diclofenac Sodium…50mg Misoprostol…200mcg
	Diary No. Date of R& I & fee	Dy.No. 12689 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID along with mucoprotective
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Arthrotec of USFDA Approved
	Me-too status	Dipros 50 Tablet by Helix (Reg. No#076456)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator	• The formulation contains misoprostol 1% HPMC dispersion & product is approved in USFDA as delayed release tablet that consists of a gastro resistant core containing 50mg of diclofenac sodium surrounded by an outer mantle containing 200mcg misoprostol along with box warning. • Firm revise formulation from plain tablet to bilayer delayed release tablet in line with reference product With submission of fee of Rs: 5000/- Deposit slip no # 2017947, dated: 03-8-2020 • For Evidence of bilayer machine firm submitted invoice from Shanghai Tianhe pharmaceuticals china
	Decision: Deferred for consideration on its turn.	
341.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Volden-M 75mg/200mcg Tablet
	Composition	Each Delayed Release Tablet Contains: Diclofenac Sodium…75mg Misoprostol…200mcg
	Diary No. Date of R& I & fee	Dy.No. 12690 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID along with mucoprotective
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Arthrotec of USFDA Approved
	Me-too status	Dipros 75 Tablet by Helix (Reg. No#076456)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16,new/additional sections " Overall evaluation of the Inspection report is rated as Good
	Remarks of the Evaluator	• The formulation contains misoprostol 1% HPMC dispersion and product is approved in USFDA as delayed release tablet that consists of a gastro resistant core containing 50mg of diclofenac sodium surrounded by an outer mantle containing 200mcg misoprostol along with box warning. • Firm revise formulation from plain tablet to bilayer delayed release tablet in line with reference product With submission

		of fee of Rs: 5000/- Deposit slip no # 2017948, dated: 03-08-2020 • For Evidence of bilayer machine firm submitted invoice from Shanghai Tianhe pharmaceuticals china
	Decision: Deferred for consideration on its turn.	
342.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Seipil ER 330mg Tablet
	Composition	Each film coated Extended Release Tablet Contains: Pregabalin…330mg
	Diary No. Date of R& I & fee	Dy.No. 13930 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's, 60's, 100's :As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA CR of USFDA approved
	Me-too status	Not found
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator	Submit Stability studies along with requisite documents.
	Decision: Deferred for consideration on its turn alongwith stability data as per requirement determined by Registration Board in 293rd meeting.	

b. Deferred cases

343.	Name and address of manufacturer / Applicant	Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad Manufactured by: Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	EPI 40mg Injection
	Composition	Each vial contain: Esomeprazole (as Sodium).....40mg
	Diary No. Date of R& I & fee	Dy. No. 5781 Date:29-08-2016 Rs. 50,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Nexium I.V. 40mg of (MHRA approved)
	Me-too status (with strength and dosage form)	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance
	Previous remarks of the Evaluator.	Contract agreement attached Number of already registred contract manufactured products: Nil
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as

		the firm has already been granted approval for contract manufacturing of numerous products **(M-282)**
	Evaluation by PEC[IV]	Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Llyophilized vial injectable (General)
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for confirmation of dry powder vial filling facility**.(M-295)**
	Evaluation by PEC[IV]	Firm replied that Lyophilization is being performed at Bio-Labs(Pvt)
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
344.	Name and address of manufacturer / Applicant	M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	Sayfon 80/80 mg Tablet
	Composition	"Each Sugar Coated Tablet Contains: Phloroglucinol DiHydrate ……..80mg Trimethyl phloroglucinol…… ……80mg"
	Diary No. Date of R& I & fee	Dy. No 14477 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Gastrointestinal Anticholinergic
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status (with strength and dosage form)	Anafortan plus tablet of M/s AGP Ltd. Karachi. Reg. No. 24504
	GMP status	"Last GMP inspection conducted on 13-02-20**18"**
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved with innovator's specification.	
345.	Name and address of manufacturer / Applicant	M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar

	Brand Name +Dosage Form + Strength	Sayfon 40/0.04 mg Injection
	Composition	"Each 4ml Ampoule Contains: Phloroglucinol Hydrate……40mg Trimethyl phloroglucinol…….0.04mg"
	Diary No. Date of R& I & fee	Dy. No 14476 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Gastrointestinal Anticholinergic
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SPASFON, solution for injection in ampoule by M/s TEVA HEALTH, (ANSM Approved)
	Me-too status (with strength and dosage form)	Spasfon Injection 4ml by M/s Himont (Reg. # 018530)
	GMP status	"Last GMP inspection conducted on 13-02-20**18"**
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved with innovator's specification.	
346.	Name and address of manufacturer / Applicant	M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Coagbon 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…..…10mg
	Diary No. Date of R& I & fee	Dy.No. 17066 dated 08-05-2018 Rs.20,000/- Dated 08-05-2018
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	10's, 14's 20's & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 10mg tablet Of (USFDA Approved)
	Me-too status (with strength and dosage form)	Xarelto 10mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 19-05-2017. And report concludes that overall firm has fair GMP compliance
	Previous remarks of the Evaluator.	Covering letter and challan form of different product submitted.
	Previous decision(s)	Deferred for submission of fee.(M-295)
	Evaluation by PEC	• Firm replies that they have already submitted the 20,000 for Registration purpose .

		• Covering letter and challan form Coagbon 10mg Tablet was attached in another product dossier.
	Decision: Approved with innovator's specification.	
347.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19 Km, Sheikhupura Road, Faislabad Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Gloricef 250mg IV/IM Injection Cefxil NeoClaf
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime……250mg
	Diary No. Date of R& I & fee	Dy.No. 33323 dated 08-10-2018 Rs.50,000/- Dated 08-10-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime powder for solution for injection of MHRA approved
	Me-too status (with strength and dosage form)	Exoran of M/s City Pharma
	GMP status	Last GMP inspection conducted on 08-10-2019 and report concludes that firm was considered to be opeating at Good level of compliance & Last GMP inspection conducted on 22-01-2019 and report concludes firm is considered to be operating at Good level of compliance of GMP requirements
	Previous remarks of the Evaluator.	• Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Previous decision(s)	Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Novamed Pharmaceuticals by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products..(M-293)
	Evaluation by PEC	Firm submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing and board after thorough deliberation decided to allow contract manufacturing from M/s Novamed Pharmaceuticals for Dry Powder Injection (cephalosporin) section
	Decision: Approved.	
348.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19 Km Sheikhupura Road, Faislabad Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Gloricef 500mg IV/IM Injection Cefxil NeoClaf

	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime……500mg
	Diary No. Date of R& I & fee	Dy.No. 33324 dated 08-10-2018 Rs.50,000/- Dated 08-10-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime powder for solution for injection of MHRA approved
	Me-too status (with strength and dosage form)	Exoran of M/s City Pharma
	GMP status	Last GMP inspection conducted on 08-10-2019 and report concludes that firm was considered to be opeating at Good level of compliance & Last GMP inspection conducted on 22-01-2019 and report concludes firm is considered to be operating at Good level of compliance of GMP requirements
	Previous remarks of the Evaluator.	• Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Previous decision(s)	Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Novamed Pharmaceuticals by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products..(M-293)
	Evaluation by PEC	Firm submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing and board after thorough deliberation decided to allow contract manufacturing from M/s Novamed Pharmaceuticals for Dry Powder Injection (cephalosporin) section. M/s Saffron pharma has 5 products already registered on contract manufacturing.
	Decision: Approved.	
349.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19 Km Sheikhupura Road, Faislabad Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd., 28-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Gloricef 1g IV/IM Injection Cefxil NeoClaf
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime……1g
	Diary No. Date of R& I & fee	Dy.No. 33325 dated 08-10-2018 Rs.50,000/- Dated 08-10-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime powder for solution for injection of MHRA approved

	Me-too status (with strength and dosage form)	Exoran of M/s City Pharma
	GMP status	Last GMP inspection conducted on 08-10-2019 and report concludes that firm was considered to be opeating at Good level of compliance & Last GMP inspection conducted on 22-01-2019 and report concludes firm is considered to be operating at Good level of compliance of GMP requirements
	Previous remarks of the Evaluator.	• Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Previous decision(s)	Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Novamed Pharmaceuticals by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products..(M-293)
	Evaluation by PEC	Firm submitted report on assessment and confirmation of manufacturing capacity for contract manufacturing and board after thorough deliberation decided to allow contract manufacturing from M/s Novamed Pharmaceuticals for Dry Powder Injection (cephalosporin) section. M/s Saffron pharma has 5 products already registered on contract manufacturing.
	Decision: Approved.	
350.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals,112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodene Solution 100mg/ml (Povidone-Iodine)
	Composition	Each ml contains: Povidone-Iodine…100mg(10%)
	Diary No. Date of R& I & fee	Dy.No 4768 dated 09-02-2018 Rs. 20,000/- Dated 09-02-2018
	Pharmacological Group	Antiseptic, germicidal
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	60ml,450ml; Rs : 77/60ml & 377/450ml
	Approval status of product in Reference Regulatory Authorities	BETADINE ANTISEPTIC TOPICAL SOLUTION povidone-iodine 100mg/mL solution
	Me-too status (with strength and dosage form)	PYODINE 10% solution by Brookes Pharma.
	GMP status	Last GMP inspection conducted on 07-01-2020., and the report concludes that " In view of above findings of inspection, areas checked, documents, documents reviewed,the panel of the opinion that firm had rectified most of the previous observation. Hence the firm allowed to resume the production activities. The management assured that they would follow the Drug act 1976 for GMP compliance
	Previous remarks of the Evaluator.	Firm applied for regularization of layout in which external preparation section is also mentioned.(Section still not approved)
	Previous decision(s)	Deferred for confirmation of required manufacturing facility / section from Licensing Division**...(M-295)**

	Evaluation by PEC	Firm submitted approval of regularization and new sections layout plan from DRAP in which External liquid preparations section mentioned
	Decision: Deferred for confirmation of required manufacturing facility / section.	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

351.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Amectin Injection
	Composition	Each ml Contains: Abamectin…….10mg
	Diary No. Date of R& I & fee	Dy.No 40619 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Reg.No. 031453 Abatek Injection 10mg M/S Star Labs,
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
352.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Selferol Injection
	Composition	Each ml Contains: Vitamin E…75mg Sodium Selenite…0.6mg
	Diary No. Date of R& I & fee	Dy.No 40611 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamin and selenium Supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml., Decontrolled
	Me-too status	Reg.No.034579 Selferol Injection Of M/S Selmore Pharmaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Selmeg
	Decision: Approved with innovator's specification.	
353.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Streplin Injection
	Composition	Each ml Contains: Procaine Penicillin G…200mg Dihydrostreptomycin Sulphate Eq. to Dihydrostreptomycin…200mg

	Diary No. Date of R& I & fee	Dy.No 40604 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml :Decontrolled
	Me-too status	Reg.No.083244 Streplin Inj of M/S Selmore Pharmaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Megapen
	Decision: Deferred for confirmation of required manufacturing facility “Liquid injectable Penicillin section” from licensing division.	
354.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tonovit Injection
	Composition	Each ml Contains: Toldimfos Sodium…200mg Vitamin B12…0.05mg
	Diary No. Date of R& I & fee	Dy.No 40614 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	10ml,Decontrolled
	Me-too status	Reg.No.033253 Tonovit Injetion Of M/S Selmore harmaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Mytovit
	Decision: Approved with innovator’s specification.	
355.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Selphos Injection
	Composition	Each ml Contains: Sodium Selenite…0.5mg Vitamin E…70mg Vitamin B12…0.1mg Vitamin B1…20mg Adenosine-5-Monophosphate…5mg
	Diary No. Date of R& I & fee	Dy.No 40612 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	10ml,Decontrolled
	Me-too status	Reg.No 029647 Selphos Injection Of M/S Selmore Pharmaceuticals

	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Myphos
	Decision: Approved with innovator's specification.	
356.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Dr.Mectin Injection
	Composition	Each ml Contains: Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 40623 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status	Not found
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Ivovectin Injection of M/s Vetz Pharmaceuticals (50ml)Reg# 079289 Each ml conatins Ivermectin…20mg Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic status) alongwith registration number, brand name and name of firm.	
357.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Icozol Injection
	Composition	Each 100ml Contains: Ricobendazole…10gm
	Diary No. Date of R& I & fee	Dy.No 40626 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml:Decontrolled
	Me-too status	Reg.No.033252 Ricozole Injection M/S Selmore Pharmaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
358.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.

	Brand Name +Dosage Form + Strength	Levamicclosan Injection
	Composition	Each 100ml Contains: Closantel sodium dihydrate…5gm Levamisole Hcl…10gm
	Diary No. Date of R& I & fee	Dy.No 40625 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Reg.No.062075 Levamiclosan Injection of M/S International Pharma Labs.,
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Levasel
	Decision: Approved with innovator’s specification.	
359.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Fospho-AV Injection
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…50mcg Taurine…37.3mg Nicotinamide…23mg DDL-Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 40617 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	RegNo.058816 Carasil Injection Of M/S Selmore Agencies
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator’s specification.	
360.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tygent Injection
	Composition	Each ml Contains: Tylosin Tartrate…100mg Gentamicin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 40618 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Reg.No.049636

		Tygent Injection Of M/S Selmore Pharmaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Gentyl
	Decision: Approved with innovator's specification.	
361.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Phosvit Injection
	Composition	Each ml Contains: Butaphosphan…100mg Vitamin B12…0.05mg
	Diary No. Date of R& I & fee	Dy.No 40616 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Reg.No.039969 Catosal 10% Injectable Solution of M/s Bayer Pakistan (Available in 100ml)
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
362.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Lidocain 2% Injection
	Composition	Each ml Contains: Lignocaine Hcl…20mg
	Diary No. Date of R& I & fee	Dy.No 40622 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Local Anaesthetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO : Decontrolled
	Me-too status	Reg.No. 041229 Lidocain 2% Injection Of M/S. International Pharma,
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Mydocain
	Decision: Approved with innovator's specification.	
363.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tylotrim Injection
	Composition	Each ml Contains: Sulphamethoxypyridazine…150mg Trimethoprim…30mg

		Tylosin Tartrate…50mg
	Diary No. Date of R& I & fee	Dy.No 40613 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Reg.No.046515 Tylotrim Injection Of M/S Selmore Pharmaceuticals,
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Cotrim
	Decision: Deferred for confirmation of Sulphamethoxypyridazine: Trimethoprim for 1:4 or 1:5 as per RRA	
364.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	BPS-LA Injection
	Composition	Each ml Contains: Procaine Penicillin G…125,000 IU Benzathine Penicillin G…100,000 IU Dihydrostreptomycin Sulphate Eq. to Dihydrostreptomycin…200mg
	Diary No. Date of R& I & fee	Dy.No 40601 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Penecilline antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml : Decontrolled
	Me-too status	Reg.No 080951 BPS-LA of M/S Selmore Pharaceuticals
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Benzapen LA
	Decision: Approved with innovator’s specification.	
365.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	I-ZVS Oral Solution
	Composition	Each 1000ml Contains: Zinc…800mg Vitamin E…150,000mg Selenium…1670mg
	Diary No. Date of R& I & fee	Dy.No 40629 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Vitamin & mineral
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1liter, 5 liter: Decontrolled
	Me-too status	Not found

	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**.**
	Decision: Deferred for following: **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **For salt form of Zinc and** Selenium	
366.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	I-Colifos-250 Oral Solution
	Composition	Each 100ml Contains: Colistin Sulphate…250,000,00 IU
	Diary No. Date of R& I & fee	Dy.No 40635 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	250ml, 500ml, 1liter, 5 liter: Decontrolled
	Me-too status	Not found
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Reg.No.082810 I-Colifos-250 Oral Solutionof M/S International Pharma Lahore(Colistin Sulphate…250,000,000 IU) Alternate brand name: • Mycostin oral solution Evidence of applied formulation/drug lready approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
367.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Clozadil Oral Suspension
	Composition	Each ml Contains: Oxyclozanide…3.4%
	Diary No. Date of R& I & fee	Dy.No 40632 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	250ml,500ml,1 Liter, 5liter: Decontrolled
	Me-too status	Reg.No.041226 Clozadil Suspension Of M/S International Pharma Lab’s.

	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator [IV]	Alternate brand name: • Oxynide Oral solution
	Decision: Approved with innovator's specification.	
368.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences. 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin D Drench
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No. 44139 dated 27-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anthlmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml, 250ml, 500ml, 1000ml ; Decontrolled
	Me-too status	Ivotek Drench 1%.Of M/S Star Laboratories Reg.# 063601
	GMP status	Last GMP inspection report dated 25-01-2018 and report concludes that firm was GMP compliant.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	
369.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences. 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Nilzan Drench Super
	Composition	Each 100ml contains: Oxyclozanide…6gm Levamisole HCL…3gm Cobalt suplhate…0.764gm Heptahydrate Sodium selenate…0.076gm
	Diary No. Date of R& I & fee	Dy.No. 44140 dated 27-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anthlmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml, 250ml, 500ml, 1000ml ; Decontrolled
	Me-too status	Leox Ds Plus Oral Suspension Of M/S Elko Organizaiton Reg.# 031595
	GMP status	Last GMP inspection report dated 25-01-2018 and report concludes that firm was GMP compliant.
	Remarks of the Evaluator [IV]	
	Decision: Approved with innovator's specification.	

Case no. 03 Registration applications of categories to be considered on priority

a. Export facilitation

Deferred cases

370.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan

	Brand Name +Dosage Form + Strength	Cefsure 2gm IM Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…2gm
	Diary No. Date of R& I & fee	Dy.No. 8527 dated 26-02-2019 Rs. 20,000 Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 2g powder of MHRA approved
	Me-too status (with strength and dosage form)	Triax 2gm Injection of M/s.Wilshire Laboratories
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Previous remarks of the Evaluator.	In generic IM or IV can not be differentiated.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. .(M-295)
	Evaluation by PEC	Firm submitted that they have mistakenly written I.M route instead of I.V now for change of formulation they submitted fee of Rs: 5000/-, Deposit slip No# 1903533 Dated : 31-08-2020
	Decision: Approved. Firm shall deposit remaining fee Rs.15000/- before issuance of registration letter.	

Case no. 04 Registration applications of import cases

a. Deferred cases

i. Human

371.	Name and address of Applicant	M/S Bristol Mayer Biotech Pakistan, 73-B Guldasht Town Lahore Cantt Pakistan
	Detail of Drug Sale License	Address : 73-B Guldasht Town, Zarar Shaheed road Lahore Validity : 07/04/2020 Status: to sell drugs in a whole sale distribution
	Name and address of manufacturer	VEM ILAC San.ve Tic. A.s. Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Faith Bulvari No: 38 Kapakli/ TEKIRDAĞ/TURKEY
	Name and address of marketing authorization holder	VEM ILAC San.ve Tic. A.s. Söğütözü Mahallesi 2177. Cadde No: 10B/49 Cankaya/Ankara/Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 33319 Dated : 08/10/2018
	Fee including differential fee	Rs : 50,000 Dated : 08/10/2018
	Brand Name +Dosage Form + Strength	Fericose 100mg/5ml I.V Solution for Injection
	Composition	Each 5ml ampoule Contains Iron as Iron Sucrose (Iron (III) Hydroxide Sucrose Complex) Eq to elemental Iron……100mg
	Finished Product Specification	USP

	Pharmacological Group	Iron Trivalent Parentral prepartions
	Shelf life	36 months
	Demanded Price	As per SRO
	Pack size	1 Vial/box
	International availability	Venofer 100mg/5ml Injection of MHRA approved
	Me-too status	Bisleri 100mg/5ml Injection of M/S Sami Pharma
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/3541 **Certified by:** Turkish Medicines and Medical devices Agency Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey Product license and date of issue : 252/21 -23 July.2013 **Valid until :** 03-10-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **GMP certificate** GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **GMP certificate and Free sale certificate** Certificate No : 2018/3635 Date of Issue: 03-10-2018 Valid until : 09-10/2020 **Sole Contract Agreement** 22-10-2018 Validity: 2 Years
	Remarks of the Evaluator.	• Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1957531 Dated: 02-12-2019 • Stability studies according to Zone IV-A not submitted.
	Previous Decision:	Deferred for following (M-295) Stability studies according to Zone IV-A not submitted.
	Evaluation by PEC	Firm submitted stability studies according to Zone IV-A, 6th month accelerated and 36th month Real time studies
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
372.	Name and address of Applicant	M/S Bristol Mayer Biotech Pakistan, 73-B Guldasht Town Lahore Cantt Pakistan
	Detail of Drug Sale License	Address : 73-B Guldasht Town, Zarar Shaheed road Lahore Validity : 07/04/2020 Status: to sell drugs in a whole sale distribution
	Name and address of manufacturer	VEM ILAC San.ve Tic. A.s. *Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Faith Bulvari No: 38 Kapakli/ TEKIRDAĞ/TURKEY*
	Name and address of marketing authorization holder	VEM ILAC San.ve Tic. A.s. *Söğütözü Mahallesi 2177. Cadde No: 10B/49 Cankaya/Ankara/Turkey*
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18447 Dated : 21/05/2018
	Fee including differential fee	Rs : 50,000 Dated : 21/05/2018 + Rs : 50000 :Dated: 16-10-2019

	Brand Name +Dosage Form + Strength	Candisept 100mg/50ml I.V Solution for Infusion	
	Composition	Each 50ml Vial Contains Fluconazole ……100mg	
	Finished Product Specification	USP	
	Pharmacological Group	Triazole antifungal derivatives	
	Shelf life	36 months	
	Demanded Price	As per SRO	
	Pack size	1 Vial/box	
	International availability	Fluconazole 2mg/ml solution for infusion of MHRA approved	
	Me-too status	Lumen 2mg/Ml Injection (50ml) Of M/S Nimrall Farma (Reg # 039823)	
	Detail of certificates attached	**<u>Valid and Legalized CoPP</u>** **Certificate No**: 2018/1719 **Certified by:** Turkish Medicines and Medical devices Agency *Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey* Product license and date of issue : 254/16 _05.11.2013 **Valid until :** 03-05-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **<u>GMP certificate and Free sale certificate</u>** Certificate No : 2018/1720 Date of Issue: 03-05-2018 Valid until : 03-05/2020 **GMP certificate:** GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **Sole Contract Agreement** 07-06-2018 Validity: 2 Years	
	Remarks of the Evaluator.	**Deficiencies/Shortcomings**	**Reply by Firm**
		Remaining fee of Rs:50000/- as product is already registered in Pakistan.	Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1914215 Dated: 16-10-2019
		Justify use of Type II glass as primary packaging material while in reference agency Type I glass is used as primary packaging material.	According to the European Pharmacopoeia "3.2.1 Glass Containers for Pharmaceuticals Use" Type II glass containers are suitable for most acidic and neutral ,aqueous prepartations whether or not for parenteral administration. Our product is near neutral and aqueous solution. Therefore, Type II glass is suitable for this product.

	Previous Decision:	Deferred for Clarification/Justification on scientific gronuds for use of Type II glass container as primary packaging material for applied formulation or otherwise evidence of reference product packed in Type II glass container **(M-293)**
	Evaluation by PEC	Firm submitted that since DRAP couldn't be convinced with explanations for use of Type II glass vials , Now VEM ILAC TURKEY will now use the type I Glass vials for Pakistan and submitted declaration from VEM Ilac Sanayi ve Ticaeret A.s that they will export their product to Pakistan with Type I glass vials.
	Decision: Regtistration Board	

Case no. 04 Registration applications of drugs for which stability study data is submitted

a. New cases

373.	Name and address of manufacturer / Applicant	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Koramngi Industrial Area Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Dexdow Delayed Release 30mg Capsules
	Composition	Each Delayed Release Capsule contains: dexlansoprazole pellets 22.5% eq to Dexlansoprazole……..60mg
	Diary No. Date of R& I & fee	Dy.No 37115 dated 09-11-2018 Rs. 100,000/- 08-11-2018
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulator Authorities	Dexilant Delayed Release Capsule 60mg of USFDA approved
	GMP status	The firm was operating at good level of compliance with GMP as per inspection report dated 06/12/2018
	Remarks of the Evaluator[4]	

STABILITY STUDY DATA	
Drug	Dexdow Delayed Release 30mg Capsules
Name of Manufacturer	M/s. Martin Dopw Limited, Plot No. 37, Sector 19, Koramngi Industrial Area Karachi, Pakistan
Manufacturer of API	M/s Vision Pharmaceuticals
API Lot No.	DLP376
Date of Submission	27-01-2020 (31664)

REMARKS OF EVALUATOR

Firm initially submitted stability data of Dexdow Delayed Release 30mg Capsules with API source from M/s Vision Pharmaceuticals, but later submitted request for withdrawal of submitted stability studies and said that they are changing the proposed source of API pellets of the said product, so it is requested to hold the evaluation till submission of revised stability studies.

Decision: Registeration Board acceded firm's request and deferred for submission of stability data as per requirement decided in 293rd meeting

374.	Name and address of manufacturer / Applicant	M/s. Martin Dopw Limited, Plot No. 37, Sector 19, Koramngi Industrial Area Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Dexdow Delayed Release 30mg Capsules
	Composition	Each Delayed Release Capsule contains: dexlansoprazole pellets 22.5% eq to Dexlansoprazole……..60mg
	Diary No. Date of R& I & fee	Dy.No 37115 dated 09-11-2018 Rs. 100,000/- 08-11-2018
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulator Authorities	Dexilant Delayed Release Capsule 60mg of USFDA approved
	GMP status	The firm was operating at good level of compliance with GMP as per inspection report dated 06/12/2018
	Remarks of the Evaluator[4]	

STABILITY STUDY DATA

Drug	Dexdow Delayed Release 30mg Capsules
Name of Manufacturer	M/s. Martin Dopw Limited, Plot No. 37, Sector 19, Koramngi Industrial Area Karachi, Pakistan
Manufacturer of API	M/s Vision Pharmaceuticals
API Lot No.	DLP376

REMARKS OF EVALUATOR

Firm initially submitted stability data of Dexdow Delayed Release 30mg Capsules with API source from M/s Vision Pharmaceuticals, but later submitted request for withdrawal of submitted stability studies and said that they are changing the proposed source of API pellets of the said product, so it is requested to hold the evaluation till submission of revised stability studies.

Decision: Registeration Board acceded firm's request and deferred for submission of stability data as per requirement decided in 293rd meeting

b. Verification of stability study data

375.	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Glusimet XR 50/500 mg Tablets
	Composition	Each film-coated tablet contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl (extended release)…500mg
	Diary No. Date of R& I & fee	Dy No. 15370: 25.04.2018 PKR 20,000/-: 25.04.2018
	Pharmacological Group	**Combinations of oral blood glucose lowering drugs**
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	5x10's; As per SRO
	Approval status of product in Reference Regulator Authorities	JANUMET XR 50/500 sitagliptin (as phosphate monohydrate)/metformin hydrochloride 50 mg/500 mg extended release tablet. TGA approved

	Me-too status	Tagipmet XR 50/500 Tablet. Reg. No. 84649
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP
	Remarks of the Evaluator	The firm was asked to submit stability data of three batches conducted in Zone IV-A. The firm did not submit the same.
	Previous Decision	Deferred for submission of stability data of of product as per decision of Registration Board **(M-290)**

STABILITY STUDY DATA

Drug	Glusimet XR 50/500 mg Tablets		
Name of Manufacturer	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi		
Manufacturer of API	**Sitagliptin as Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. **Metformin HCl:** M/s Aarti Drugs Limited, (Unit-II) , India		
API Lot No.	**Sitagliptin as Phosphate Monohydrate:** M-20181222-D06-M06-05 **Metformin HCl:** MEF/18122466		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,,6 (month) Real Time: 0,3,6 (month)		
Batch No.	068B19	069B19	070B19
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	22-04-2019	22-04-2019	22-04-2019
Date of Initiation	23-05-2019	23-05-2019	23-05-2019
No. of Batches	03		
Date of Submission	30-01-2020 (32248)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**Sitagliptin as Phosphate Monohydrate:** Copy of COA (Batch# M-20181222-D06-M06-05) from M/s Fuxin Long Rui pharmaceutical Co., Ltd. China is submitted. **Metformin HCl:** Copy of COA (Batch# MEF/18122466) from M/s Aarti Drugs (Unit-II) Limited, valsad Gujrat, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sitagliptin as Phosphate Monohydrate:** Copy of Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui

		Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug Administration of the People's Republic of China is submitted, valid upto 20-12-2022 **Metformin HCl:** M/s Aarti Drugs (Unit-II) Limited: Copy of GMP Certificate (Certificate#. 1801541) issued by Food and Drug Control Administration, India valid upto 09-01-2020 is submitted
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Sitagliptin as Phosphate Monohydrate:** Copy of form 5 & Commercial Invoice No HN190223-G Dated: 28-02-2019 from Beijing Sino Hanson Import & Export is submitted & attested by ADC (Karachi) dated ;19-07-2018. **(** Decleration submitted that Fuxin long Rui inform that their product would be exported under their sister company Beijing Sino Hanson Import & Export) **Metformin HCl:** Copy of form-5 & Commercial Invoice No: EXP/1945/18-19-27/12/2018 Dated: 17-12-2018 from Aarti Drugs Limited, is submitted & attested by ADC(Karachi) dated ;11-01-2019
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

i. Applied technology of Active coating for Sitagliptin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride.

ii. Method development study to justify 10% overage of Sitagliptin in master formulation (which is required to be based on study/scientific rationale)

376.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name +Dosage Form + Strength	Glusimet XR 50/1000 mg Tablets
	Composition	Each film-coated tablet contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl (extended release)…1000mg
	Diary No. Date of R& I & fee	Dy No. 15371: 25.04.2018 PKR 20,000/-: 25.04.2018

	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed manufacturer‘s specifications
	Pack size & Demanded Price	5x10‘s; As per SRO
	Approval status of product in Reference Regulator Authorities	JANUMET XR 50/1000 sitagliptin (as phosphate monohydrate)/metformin hydrochloride 50 mg/500 mg extended release tablet. TGA approved
	Me-too status	Tagipmet XR 50/1000 Tablet. Reg. No. 84650
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP
	Remarks of the Evaluator	The firm was asked to submit stability data of three batches conducted in Zone IV-A. The firm did not submit the same.
	Previous Decision	Deferred for submission of stability data of product as per decision of Registration Board **(M-290)**

STABILITY STUDY DATA

Drug	Glusimet XR 50/1000 mg Tablets		
Name of Manufacturer	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi		
Manufacturer of API	**Sitagliptin as Phosphate Monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. **Metformin HCl:** M/s Aarti Drugs Limited, (Unit-II) , India		
API Lot No.	**Sitagliptin as Phosphate Monohydrate:** M-20181222-D06-M06-05 **Metformin HCl:** MEF/18122466		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,,6 (month) Real Time: 0,3,6 (month)		
Batch No.	071B19	072B19	073B19
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	22-04-2019	22-04-2019	22-04-2019
Date of Initiation	23-05-2019	23-05-2019	23-05-2019
No. of Batches	03		
Date of Submission	30-01-2020 (32247)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
9.	COA of API.	**Sitagliptin as Phosphate Monohydrate:** Copy of COA (Batch# M-20181222-D06-M06-05) from M/s Fuxin Long Rui pharmaceutical Co., Ltd. China is submitted. **Metformin HCl:**

		Copy of COA (Batch# MEF/18122466) from M/s Aarti Drugs (Unit-II) Limited, valsad Gujrat, India is submitted.
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sitagliptin as Phosphate Monohydrate:** Copy of Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug Administration of the People's Republic of China is submitted, valid upto 20-12-2022 **Metformin HCl:** M/s Aarti Drugs (Unit-II) Limited: Copy of GMP Certificate (Certificate#. 1801541) issued by Food and Drug Control Administration, India valid upto 09-01-2020 is submitted
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	**Sitagliptin as Phosphate Monohydrate:** Copy of form 5 & Commercial Invoice No HN190223-G Dated: 28-02-2019 from Beijing Sino Hanson Import & Export is submitted & attested by ADC (Karachi) dated ;19-07-2018. **(** Decleration submitted that Fuxin long Rui inform that their product would be exported under their sister company Beijing Sino Hanson Import & Export) **Metformin HCl:** Copy of form-5 & Commercial Invoice No: EXP/1945/18-19-27/12/2018 Dated: 17-12-2018 from Aarti Drugs Limited, is submitted & attested by ADC(Karachi) dated ;11-01-2019
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes
REMARKS OF EVALUATOR		
i. Applied technology of Active coating for Sitagliptin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride. ii. Method development study to justify 10% overage of Sitagliptin in master formulation (which is required to be based on study/scientific rationale)		
Report on Investigation of Authenticity / Genuineness of data submitted for registration of Glusimet XR (Sitagliptin + Metformin) 50mg/500mg & 50mg/1000mg Tablets by M/s Scilife Pharma Pvt. Limited, Plot # FD-57/58-A2, KCIP, Karachi.		

Reference No: F.1-2/2020-PEC dated 6th July, 2020.
Investigation Date and Time: 16th July, 2020. (Forenoon)
Investigation Site: Factory premises of M/s Scilife Pharma Pvt. Ltd. Plot # FD-57/58-A2, KCIP, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Scilife Pharma Pvt. Ltd. Plot # FD-57/58-A2, KCIP, Karachi for registration of Glusimet XR (Sitagliptin + Metformin) 50mg/500mg & 50mg/1000mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration. It was also advised to verify:

a. Applied technology of Active coating for Sitagliptin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride.
b. Product development study to justify 10%overage of Sitagliptin in master formulation (which is required to be study/scientific rationale)

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board).
2. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.
3. Dr. Asfandyar Ajab Khan, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Glusimet XR 50/500mg and 50/1000mg tablets

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Material used from commercial import of 50 kg Sitagliptin Phosphate monohydrate imported from M/s Fuxin long Rui Pharmaceutical co. Limited China taken ADC approval 08-03-2019 Invoice No HN190228-C Dated: 28-02-2019 and 2000 Kg Metformin HCl from M/s Aarti Drugs ltd. India taken ADC approval 11-01-2019 Invoice No. EXP/1945/18-19-27/12/2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm. The parameters included in this form are, DMF status, GMP certificate, Stability data, provision of reference standard of APIs and impurities standards etc. The firm has evaluated on these criteria and both the APIs qualified and selected accordingly.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has documents confirming the import of USP reference standards of Sitagliptin Phosphate and Metformin HCl having ADC approval 14-11-2018 invoice no.

		19BGST48458 Dated 23-10-2018 while impurity standard received directly from manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis of both APIs, USP reference standards and impurity standard.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP certificates of both APIs manufacturers issued by regulatory authorities of their respective country of origin.
6.	Do you use API manufacturer method of testing?	Firm has used API manufacturer`s method of testing for Sitagliptin Phosphate monohydrate and Metformin HCl has been tested as per USP monograph.
7.	Do you have stability studies reports on API?	Firm has stability studies reports on both APIs provided by the respective manufacturers
8.	If yes, whether the stability testing have been performed as per SIM method and degradation products have been quantified?	Stability testing performed as per Stability Indicating Methods (SIM) and impurities/related substances/degradation products quantified for both APIs by their respective manufacturers.
9.	Do you have method for quantifying the impurities in the API?	The firm has used manufacturer methods for Sitagliptin Phosphate monohydrate and USP method for Metformin HCl. Both the methods have the capability to quantifying the respective impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of both the APIs, their reference standards and impurity standards.
11.	Have you used pharmaceutical grade excipients?	Firm has used pharmaceutical grade excipients including Hypromelloe, Microcrystalline Cellulose, Aerosil 200, Sodium Stearyl Fumarate, HPMC 6CPS, Kaolin, PEG 6000, Povidone K30, Titanium dioxide, Talc, Propyl Gallate and Opadry Blue.
12.	Do you have documents confirming the import of the used excipients?	Firm has documents confirming the import of excipients used except the one purchase from the local market. All necessary documents and certificate of analysis available with them.
13.	Do you have test reports and other records on the excipients used?	Firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocol for the development of the product?	Firm has written and authorized protocol for the development of the product.

<table>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>Firm has not performed Drug-excipients compatibility studies, as their formulation is similar to that of the innovator formulation (Janumet XR M/s MSD).</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm has performed comparative dissolution studies with Janumet XR tablets manufactured by M/S. MSD. The firm‘s product results are comparable to that of the Reference product.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>Firm has equipped product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment’s available in product development section for development of the product?</td><td>Firm has necessary equipment for manufacturing of tablets in product development section. However, primary packaging (blistering) performed in commercial production area.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The relevant equipment in product development section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>Firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has trained and qualified staff in product development section with proper knowledge and training in product development Including 03 Pharmacist, 05 Chemist and 01 Bio technologist.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches for the stability studies of Glusimet XR 50/500mg and Glusimet XR 50/1000mg tablets respectively. The details are given below,
<table>
<tr><th rowspan="2">S. #</th><th colspan="2">Glusimet 50/500mg</th><th colspan="2">Glusimet 50/1000mg</th></tr>
<tr><th>B. No.</th><th>B. Size</th><th>B. No.</th><th>B. Size</th></tr>
<tr><td>1</td><td>068B19</td><td>1000</td><td>071B19</td><td>1000</td></tr>
<tr><td>2</td><td>069B19</td><td>1000</td><td>072B19</td><td>1000</td></tr>
<tr><td>3</td><td>070B19</td><td>1000</td><td>073B19</td><td>1000</td></tr>
</table>
</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals) and minimum workingCapacity of the equipment.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Firm has completed record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Firm has approved detailed protocol for stability testing of stability batches.</td></tr>
</table>

26.	Do you have developed and validated the method for testing of stability batches?	The Firm has developed and performed detailed analytical method validation studies for testing of stability batches.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The firm has not conducted method transfer studies; however, they have validated their method properly.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	Firm has proper documents confirming the qualification of equipment / instruments used in the test and analysis of API and the finished drug.
29.	Do your method of analysis stability indicating?	Method of analysis is stability indicating as supported by force degradation studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record of the firm. Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.
31.	Can you show Audit Trail reports on product testing?	Audit trail reports were available and randomly checked.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	Firm has completed the accelerated stability testing on the three stability batches however; the real time stability testing is in progress on all the three stability batches. Currently 12 months study completed showing satisfactory results.
34.	Do you have valid calibration status for the equipment's used in production and analysis?	Firm has valid calibration status for the equipment used in production and analysis of the product.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant.
37.	Additional points: a. Applied technology of Active coating for Sitagliptin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride. b. Product development study to justify 10%overage of	a. Since in this formulation the core tablet of metformin hydrochloride developed as sustained release form, while the Sitagliptin taken as immediate release form in which Sitagliptin is loaded via coating solution on the sustained released core tablet of metformin hydrochloride same as that of innovator formulation JANUMET XR TABLETS.

	Sitagliptin in master formulation (which is required to be study/scientific rationale)	b. Sitagliptin is immediate release part of the product in which drug is loaded via coating solution on the sustained release core tablet of metformin hydrochloride. The coating process has the loss of the coating solution as the coating solution remains in the coating pan, adhere with the walls of the coating pan and de-dusting through exhaust during the coting process. The firm performed a study and developed scientific rationale that the 10% overage of Sitagliptin in the coating solution give the 100% Sitagliptin in the final finished product. This 10% excess considered as process loss rather than overages, which is satisfactory. However the overage will be, minimized after validation at commercial stage.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Glusimet XR (Sitagliptin + Metformin) 50mg/500mg & 50mg/1000mg Tablets is verifiable to satisfactory level.

2. The related manufacturing area, equipment, personnel and utilities are compliant to GMP standards and are suited for the manufacturing of Glusimet XR (Sitagliptin + Metformin) 50mg/500mg & 50mg/1000mg Tablets.

Decision: Registration Board decided to approve registration of Glusimet XR (Sitagliptin + Metformin) 50mg/500mg & 50mg/1000mg Tablets with Innovator's specifications by M/s Scilife Pharma. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

377.	Name and address of manufacturer / Applicant	M/s. Sami Phmaceuticals (Pvt) Limited, F-95, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Provas AS Tablet
	Composition	Each film coated tablet contains: Paracetamol BP ……..325mg Diphenhydramine HCl BP…….25mg Phenylephrine HCl BP……5mg
	Diary No. Date of R& I & fee	Dy.No. 15668 ; Dated:07-03-2019; Rs 50000/- 04-03-2019
	Pharmacological Group	Pain reliever Antihistamine Nasal decongestan
	Type of Form	Form 5D
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	Sever Allergy Plus Sinus Headach of USFDA OTC product.
	GMP status	GMP certificate issued dated: 14-06-2018
	Remarks of the Evaluator	

S.no	Deficiencies/Shortcomings	Reply by Firm
1.	Reference provided is of OTC drug which is not	a) In our case, reference drug of PROVAS-AS Tablets is **Severe Allergy Plus Sinus Headache Tablets**, which is an OTC drug holding NDC 49035-543

	available in USFDA database. DISCLAIMER available is that: **"**OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies**".** Clarify/Justify before further processing the case.	labeled by Wal-mart Stores Inc. In PORVAS-AS; all active ingredients and their composition are the same as of Severe Allergy Plus Sinus Headache (OTC drug) whose individual ingredients viz., Paracetamol, Diphenhydramine & Phenylephrine are approved and available as individual monograph in Federal Register b) FDA's review of OTC drugs is primarily handled by CDER's Office of Drug Evaluation IV. There are more than 80 therapeutic categories of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, CDER oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks The Nonprescription Drug Advisory Committee meets regularly to assist the agency in evaluating the issues surrounding these products. This committee has played a major role in the growth of prescription to OTC switches in recent years Sure there are over 300,000 marketed OTC drug products, FDA reviews the active ingredients and labeling of over 80 therapeutic classes of drugs, e.g. analgesics, antacids, instead of individual drug products. For each category, an OTC drug monograph is developed and published in the Federal Register. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling. Many of these monographs are found in section 300 of the Code of Federal Regulations. Once a final monograph is implemented, companies can make and market an OTC product without the need for FDA pre-approval. These monographs define the safety, effectiveness, and labeling of all marketing OTC active ingredients ***- Annexure-A*** c) Please note new products that conform to a final monograph may be marketed without further FDA review. Those which do not conform are reviewed by the New Drug Application process; a drug company may also petition to change a final monograph to include additional ingredients or to modify labeling The NDC Product information enclosed herewith contains FDA Application Number: part 341 (for OTC drugs, it is CFR citations corresponding to appropriate Monograph e.g. "part 341", for unapproved drugs this field will be null) ***- Annexure B*** d) It is further clarified that an NDA may be submitted for a direct-to-OTC drug product while many

		FDA-approved OTC drug products (i.e., OTC products that have an approved NDA) begin their lifecycle as NDA-approved prescription drugs and then eventually switch to OTC status under the NDA provisions; it is commonly referred to as an Rx-to-OTC switch; numerous products including CLARITIN (Loratidine) NEXIUM (Esomeprazole) etc. are further example of it; **approved by FDA as prescription drug initially and later switched to OTC (reference enclosed herewith)** - ***Annexure C*** e) It is pertinent to add that DRAP is also following the same principle in case of Iron preparations. Copies of M-282, M-284, M-286 & M-287 minutes of Drug Registration Board are enclosed in this context for your kind perusal – ***Annexure D***

STABILITY STUDY DATA

Drug	Provas AS Tablet		
Name of Manufacturer	M/s. Sami Phmaceuticals (Pvt) Limited, F-95, S.I.T.E. Karachi.		
Manufacturer of API	**Paracetamol:** Hebei Jiheng (Group) Pharmaceuticals co., Ltd China **Diphenhydramine HCl:** Supriya Lifesciences Ltd, India **Phenylephrine HCl:** Shenzen Oriental Pharmaceuticals co., Ltd China		
API Lot No.	**Paracetamol :** 31709016 **Diphenhydramine HCl :**SLL/DPH/1215076 **Phenylephrine HCl :** PEH-180101Y1		
Description of Pack (Container closure system)	Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,,6 (month) Real Time: 0,3 ,6, 9 (month)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	07- 2018	07- 2018	07- 2018
No. of Batches	3		
Date of Submission	07-03-2019 (Dy. No. 15668) 22-08-2019(DY. No. 15311)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
17.	COA of API.	**Paracetamol:** Copy of COA by Hebei Jiheng (Group) Pharmaceuticals co., Ltd china is submitted
		Diphenhydramine HCl: Copy of COA by Supriya Lifesciences Ltd, India is submitted
		Phenylephrine HCl: Copy of COA by Shenzen Oriental Pharmaceuticals co., Ltd China is submitted

18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Paracetamol:** Copy of GMP Certificate No. HE20160062 by Food & Drugs control Adminstration China. valid till 14-11-2021.
		Diphenhydramine HCl: Copy of GMP Certificate No. NEW-WHO-GMP/CERT/KD/67649/2018/11/25185 by Food & Drugs control Adminstration , M.S, Bandra, Mumbai. Maharashtra. India. valid till 04-10-2021.
		Phenylephrine HCl: Copy of GMP Certificate No. GD20150448 by Food & Drugs control Adminstration China. valid till 07-12-2022.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	**Paracetamol:** Copy of Commercial Invoice No 1708ZP03 Dated: 19-10-2017 by Hebei Jiheng (Group) Pharmaceuticals co., Ltd China is submitted attested by ADC (Karachi) dated ;01-11-2017.
		Diphenhydramine HCl: Copy of Commercial Invoice No SLL/EXP/899/15-16 Dated: 25-03-2016 by Supriya Lifesciences Ltd, India is submitted attested by ADC(Karachi) dated ;13-04-2016.
		Phenylephrine HCl: Copy of Commercial Invoice No SZ-1804052 Dated: 11-04-2018 by Shenzen Oriental Pharmaceuticals co., Ltd China is submitted attested by ADC (Karachi) dated ;06-07-2018.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

S.no	Deficiencies/Shortcomings	Reply by Firm
1.	GMP certificate of source of all API(s)	Submitted.
2.	Unidentified peaks & inverted peaks are appearing in Phenylephrine assay and dissolution in all time points . Please justify.	This product conatins 3 API's i.e Paracetamol, Diphenhydramine HCl and Phenyephrine HCl the identified peaks are response of paracetamol and Diphenhydramine HCl

3.	Retention time are varying on different time points for same sample .Please clarify.	Slight variation in the retention time may be observed due to multiple factors but not affecting the result. We have done the complete method validation of this testing method as per USP/ICH and method comply all the parametrs.
4.	Jusification is required for dissolution parameters including i. Dissolution apparatus ii. RPM iii. Dissolution parameters iv. Sampling time	Dissolution parameters are extracted from pharmacopeal monograph of similar product that contains Acetaminophen (Paracetamol), diphenhydramine and Pseudoephedrine tablet
5.	Jusification is required for assay of paracetamol, Diphenhydramine and phenylephrine as you have used two testing method	Method of analysis for Assay of Paracetamol and Diphenhydramine are derived from the pjharmacopeal method of Acetaminophen (Paracetamol), diphenhydraime and Pseudoephedrine while for phenylephrine HCl, method of raw material is used.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Tefod 25mg Tablets in its 288th Meeting • Date of Inspection: 28-01-2019 • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol:** Copy of Commercial Invoice No 1708ZP03 Dated: 19-10-2017 by Hebei Jiheng (Group) Pharmaceuticals co., Ltd China is submitted attested by ADC (Karachi) dated ;01-11-2017.
		Diphenhydramine HCl: Copy of Commercial Invoice No SLL/EXP/899/15-16 Dated: 25-03-2016 by Supriya Lifesciences Ltd, India is submitted attested by ADC(Karachi) dated ;03-04-2016.
		Phenylephrine HCl: Copy of Commercial Invoice No SZ-1804052 Dated: 11-04-2018 by Shenzen Oriental Pharmaceuticals co., Ltd China is submitted attested by ADC (Karachi) dated ;06-07-2018.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted photocopy of Invoices for the procurement of reference standard and impurity standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Paracetamol:** Copy of GMP Certificate No. HE20160062 by Food & Drugs control Adminstration China. valid till 14-11-2021.
		Diphenhydramine HCl:

<table>
<tr><td></td><td></td><td>Copy of GMP Certificate No. NEW-WHO-GMP/CERT/KD/67649/2018/11/25185 by Food & Drugs control Adminstration , M.S, Bandra, Mumbai. Maharashtra. India. valid till 04-10-2021.</td></tr>
<tr><td></td><td></td><td>Phenylephrine HCl:
Copy of GMP Certificate No. GD20150448 by Food & Drugs control Adminstration China. valid till 07-12-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from all APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted
COA of API:
Paracetamol : 31709016
Diphenhydramine HCl :SLL/DPH/1215076
Phenylephrine HCl : PEH-180101Y1
COA of Reference Standard:
Paracetamol CRS
Phenyephrine Hydrochloride CRS
Diphenhydramine Hydrochloride CRS
Diphenhydramine Impurity A CRS
Leaflet from EDQM submitted.
Acetaminophen related Compound J Lot No# LRAA9623 COA by sigma- Aldrich submitted.
Acetaminophen Related Compond F Lot No# F0M236
M-Aminophenol Lot G0J290
Leaflet from USP Submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted commercial invoices & COAs of all the excipients used in formulation of Provas As Tablet, from relevant manufacturers</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table><tr><td colspan="3">Provas AS Tablet</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>Lab-01</td><td>2500 tablets</td><td>06-2018</td></tr><tr><td>Lab-02</td><td>2500 tablets</td><td>06-2018</td></tr><tr><td>Lab-03</td><td>2500 tablets</td><td>06-2018</td></tr></table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches. The detail is as under:
<table>
<tr><th>Batch No.</th><th>Total no. of tablets for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr>
<tr><td>Lab-01</td><td>1655</td><td>440</td><td>1215</td></tr>
<tr><td>Lab-02</td><td>1655</td><td>440</td><td>1215</td></tr>
<tr><td>Lab-03</td><td>1655</td><td>440</td><td>1215</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 12-07-2018 to 18-01-2019 and for Real Time stability chamber starting from 12-07-2018 to 18-01-2019</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 06 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Paracetamol: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 75±5%RH) stability study reports of 03 batches.
Diphenhydramine HCl: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 75±5%RH) stability study reports of 03 batches.
Phenylephrine HCl : The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 75±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Drug-excipients compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “ Brilinta”. The details are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of High-Q</th></tr>
<tr><td>Brand name</td><td>Equate sever Allergy Plus</td><td>Provas AS Tablet</td></tr>
</table></td></tr>
</table>

		<table><tr><td></td><td>Sinus Headach</td><td></td></tr><tr><td>Batch No.</td><td>P111532</td><td>Lab-01</td></tr></table> Comparative dissolution studies have been performed in following mediums: 1. pH 1.2 HCl buffer 2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches

Remarks of Evaluator:

S.no	Deficiencies/Shortcomings	Reply by Firm
1.	Composition of Paracetamol 326.7951mg & Diphenhydramine 25.16mg while label claim for Paracetamol 325mg & Diphenhydramine 25mg. Clarify.	The quantity of API(Paracetamol) as per label is 325mg/tablet whereas the calculated quanitity of API is 326.7951mg/tablet which is according to its potency. However, the quanitity of API per tablet will remain same as of label claim i.e, 325mg/tablet. The quantity of API(Paracetamol) as per label claim is 25mg/tablet whereas the calculated quanitity of API is 25.16mg/tablet which is according to its potency. However, the quanitity of API per tablet will remain same as of label claim i.e, 25mg/tablet.
2.	Authorized P rotocols/SOP for the development & stability testing of trial batches not submitted.	Submitted
3.	COA of reference standards and impurity standards not submitted.	Firm submitted leaflet from EDQM and submit reply that EDQM does not provide certificate of analysis for European Pharmacopeia reference standard. The EDQM provides an information leaflet that contains all of the information need to carry out the testes and assays described in the related monographs Two different leaflets are being attached therein, Potency has been provided in one leaflet whereas another leaflet doesn't mention potency.
4.	COA of maiz starch not signed by manufacturer.	COA is generated by system and needs no sign.
5.	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> throughout stability studies. Justification shall be submitted in this regard.	Content uniformity testing performed in july 2018 of 3 batches Lab-01,Lab-02& Lab-03 submitted.
6.	F2 calculation for phenylephrine in comparative dissolution not submitted.	F2 calculation for phenylephrine in comparative dissolution submitted.
7.	Accelerated stability studies for API Phenylephrine according to Zone IV-A not submitted.	Submitted

8.	Accelerated stability & long term studies for Paracetamol are of different batches. Clarify.	Because the Accelerated stability testing condition of IV zone B is same as the Accelerated stability testing condition of I and II (temperature 40°C ± 2°C & 75±5%RH) so for Accelerated stability testing , we didn't do for Batch 011703029/011710020/011710019.
9.	In accelerated stability , auditrail for assay at 4th month not submitted..	Submitted.

Previous Decision(M-293):

Registration board decided to consider the case after onsite inspection by the panel for verification of authenticity of submitted stability studies data due to following observation in the stability data:

- Unidentified peaks & inverted peaks are appearing in Phenylephrine assay and dissolution in all time points.
- Retention time are varying on different time points for same sample.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Provas AS (Paracetamol, Phenylephrine HCl and Diphenhydramine HCl) Tablets by M/s Sami Pharmaceuticals Pvt. Limited, Karachi.

Reference No: F.1-2/2020-PEC dated 18th February, 2020.
Investigation Date and Time: 28th June, 2020. (Forenoon)
Investigation Site: Factory premises of M/s Sami Pharmaceuticals Pvt. Ltd. Karachi.

Background:

Registration Board in its 293rd meeting considered the applications of M/s. Sami Pharmaceuticals (Pvt.) Ltd., Karachi for registration of Provas AS (Paracetamol, Phenylephrine HCl and Diphenhydramine HCl) Tablets and constituted a two member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

1. Unidentified peaks and inverted peaks are appearing in Phenylephrine assay and dissolution in all time points.
2. Retention time are varying in different time points for same sample.

Composition of Panel:

1. Dr. Sidra Yasmeen, Assistant Director, Drug Regulatory Authority of Pakistan, Karachi.
2. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Details of Investigation:

S. No.	Questions	Remarks

<table>
<tr>
<td>1.</td>
<td>Do you have documents confirming the import API including approval from DRAP?</td>
<td>
<table>
<tr><th>API</th><th>Supplier</th><th>Batch No</th><th>Invoice No</th><th>Received Qty.</th></tr>
<tr><td>Paracetamol</td><td>Hebei Jiheng (Group) Pharmaceutical Co. Ltd.</td><td>31709016</td><td>1708ZP03</td><td>5000 Kg</td></tr>
<tr><td>Phenylephrine Hydrochloride</td><td>Shenzhen Oriental Pharmaceutical Co. Ltd.</td><td>PEH-180101Y1</td><td>SZ-1804052</td><td>100gm</td></tr>
<tr><td>Diphenhydramine</td><td>Supriya Lifescience Ltd.</td><td>SLL/DPH/1215076</td><td>SLL/EXP/899/15-16</td><td>0.700 kg</td></tr>
</table>
The firm has obtained proper approval from DRAP Karachi.
</td>
</tr>
<tr>
<td>2.</td>
<td>What was the rationale behind selecting the particular manufacturer of API?</td>
<td>There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through:

Desktop Audit checklist
GMP approval by competent authority

</td>
</tr>
<tr>
<td>3.</td>
<td>Do you have documents confirming the import of API reference standard and impurity standards?</td>
<td>The firm has imported the following reference standard and impurities standard.
<table>
<tr><th>Reference |Standard</th><th>Supplier /Source</th><th>Batch No.</th><th>Quantity</th></tr>
<tr><td>Acetaminophen related compound F</td><td>USP</td><td>F0M236</td><td>50mg</td></tr>
<tr><td>m-Aminophenol</td><td>USP</td><td>G0J290</td><td>300mg</td></tr>
<tr><td>Paracetamol CRS</td><td>EDQM</td><td>Batch No. 4</td><td>50mg</td></tr>
<tr><td>Phenylephrine HCl for peak identification CRS</td><td>EDQM</td><td>Batch No. 5</td><td>2mg</td></tr>
<tr><td>Phenylephrine HCl CRS</td><td>EDQM</td><td>Batch No. 3</td><td>50mg</td></tr>
<tr><td>Diphenhydramine HCl CRS</td><td>EDQM</td><td>Batch No. 1</td><td>100mg</td></tr>
<tr><td>Diphenhydramine Impurity A CRS</td><td>EDQM</td><td>Batch No. 4</td><td>10mg</td></tr>
</table>
</td>
</tr>
</table>

		4-Chloroacetanilide (Acetaminophen RCJ) pharmaceutical secondary standard	Sigma Aldrich	LRAA9623	1g
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Firm have certificates of analysis for API, reference standards and impurity standards			
5.	Do you have GMP certificate of APIs manufacturer issued by regulatory authority of country of origin?	Firm has GMP certificate for Paracetamol of M/s. Hebei Jiheng (Group) Pharmaceutical Co. Ltd. issued by Hubei Food and Drug administration – China, Diphenhydramine HCl of M/s. Supriya Lifescience Ltd issued by M/S. Bandra (E) Mumbai. Maharashtra state -India. Phenylephrine Hydrochloride of M/s. Shenzhen Oriental Pharmaceutical Co. Ltd issued by Food and Drug administration – China.			
6.	Do you use APIs manufacturer method of testing for testing APIs?	Firm has used pharmacopoieal method of testing for APIs.			
7.	Do you have stability studies reports on API?	The firm has stability studies report of APIs, Paracetamol, Phenylephrine HCl, Diphenhydramine HCl conducted by API manufacturer.			
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of API has performed the stability studies of APIs as per SIM Method and the Related Substance have been quantified by the API manufacturer			
9.	Do you have method for quantifying the impurities in the API?	The firm has methods for quantifying the impurities in API.			
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has 440g of Diphenhydramine HCl and 44g Phenylephrine HCl but has consumed all reference standards and impurity standards.			
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients			
12.	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import of the used excipients.			
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients.			
14.	Do you have written and authorized protocols for the development of Provas AS Tablets.?	The firm has written and authorized protocol for the development of Provas AS Tablets.			
15.	Have you performed Drug-excipients compatibility studies?	The firm has used same excipients as used by the innovator. However, compatibility studies were also performed for maximum assurance.			

<table>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative studies with innovator Equate (Severe Allergy Plus Sinus Headache) Tablet, distributed by Wal-Mart Store Inc, Bentonville, AR 72716.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) Section with the facility of manufacturing and Analysis of R&D products.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Provas AS Tablets.?</td><td>The firm has necessary equipment available in product development section for development of Provas AS Tablet.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>The available equipment in Product Development are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>There is proper maintenance / calibration program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has 10 Pharmacists and 01 Chemists for Product Development Formulation and 6 Pharmacist and 4 Chemists in Analytical section.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Provas AS Tablets.as required?</td><td>The firm has manufactured three stability batches of each 2500 tablets.
<table>
<tr><th colspan="3">Provas AS Tablet</th></tr>
<tr><td>Batch No</td><td>Date of Mfg.</td><td>Expiry Date</td></tr>
<tr><td>Lab-01</td><td>06-2018</td><td>05-2020</td></tr>
<tr><td>Lab-02</td><td>06-2018</td><td>05-2020</td></tr>
<tr><td>Lab-03</td><td>06-2018</td><td>05-2020</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches are the number of Tablets per testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record for the stability batches of Provas AS Tablet.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has protocols for testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method of testing of finish product Provas AS Tablet, based on method of testing of API.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Method transfer studies are not applicable as the firm developed and validated their own method.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Provas AS tablets.</td></tr>
<tr><td>29.</td><td>Does your method of analysis stability indicate?</td><td>The firm’s Method of analysis is Stability indicating supported by forced degradation.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software’s are 21CFR compliant.</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports?</td><td>The firm has audit trail Reports on testing.</td></tr>
</table>

32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has some remaining quantities of stability batches only.
33.	Do you have stability batches kept on stability testing?	The firm has three stability batches kept on stability for Real time stability testing. 18 Months Real Time and 6 months Accelerated stability studies has been completed.
34.	Do you have valid calibration status for the equipments used in Provas AS Tablets production and analysis?	The firm has valid calibration status for the equipment used in Provas AS Tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through 21CFR compliant software.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are rated as GMP compliant.
37.	Any other query raised by Registration Board: 1. Unidentified peaks and inverted peaks are appearing in Phenylephrine assay and dissolution in all time points. 2. Retention time are varying in different time points for same sample.	1. The panel reviewed the investigation performed by the firm which concluded as on the basis of study the unidentified peaks are of Paracetamol and Diphenhydramine HCl, which are also observed in the submitted dossier. However, the estimation of Phenylephrine HCl was not affected due to these peaks. 2. The panel also reviewed investigation of the firm for varying retention time, the firm has performed root cause analysis and concluded as the change in retention time was due to addition of freshly prepared mobile phase due to less amount of mobile phase, the firm changed the protocol and started preparing double amount of mobile phase initially so that such events may not occur again. The panel reviewed the data of the firm for later time points of real time stability studies and found the product stable and satisfactory.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Provas AS (Paracetamol, Phenylephrine HCl and Diphenhydramine HCl) Tablets is verifiable to highly satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are compliant are suited for the manufacturing of Provas AS Tablets.

Decision: Registration Board decided to approve registration of Provas AS Tablets(Paracetamol ..325mg, Diphenhydramine HCl ..25mg, Phenylephrine HCl ..5mg).with Innovator's specifications by M/s Sami Phmaceuticals. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case no. 05 Miscellaneous cases

378.	Name and address of manufacturer / Applicant	M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	Oxab 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine…….150mg

	Diary No. Date of R& I & fee	Dy.No. 16639 dated 07-05-2018 Rs.20,000/- Dated 07-05-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status (with strength and dosage form)	Telox 150mg Tablets of M/S Platinum Pharmaceutical,
	GMP status	"Last GMP inspection conducted on 13-02-20**18"**
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-290)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Previous Decision (M-293): Decision was not recorded.	
	Decision: Approved.	

Agenda of Evaluator PEC-XI

Case no. 01 Registration applications for local manufacturing of (Human) drugs

New cases

379.	Name and address of manufacture / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Jfenac P 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7521 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Valron-P 75 tablets by M/s Venus Pharma (Reg#078831)
	GMP Status	The firm was inspected on 18-07-2017 and conclusionof inspection was: Based on areas inspected, documents checked and interaction with the management the firm M/s Jawa Pharmaceuticals Pvt Ltd Lahore was considered to be operating **at the satisfactory level of GMP** compliance as per Drugs, Act, 1976 and rules framed thereunder.

	Remark of the Evaluator [XI]	• The firm provided the evidence of **cataflam tablets USFDA** approved which could not be verified in the applied strength • The firm revised master formulation and replaced methylene chloride with IPA in coating composition. • Upon clarification for addition of 5% overage the firm replied that they use 5% excess of active material to make their product more effective and stable.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
380.	Name and address of manufacture / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Jfenac 100mg SR Tablet
	Composition	Each Tablet Contains: Diclofenac Sodium…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7524 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	VOLTAREN-XR (diclofenac sodium film coated extended-release) tablets 100mg, (USFDA Approved) **Discontinued** **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Heltron SR Tablets 100mg by M/s Heal Pharmaceuticals (Reg#84235)
	GMP Status	The firm was inspected on 18-07-2017 and conclusionof inspection was: Based on areas inspected, documents checked and interaction with the management the firm M/s Jawa Pharmaceuticals Pvt Ltd Lahore was considered to be operating **at the satisfactory level of GMP** compliance as per Drugs, Act, 1976 and rules framed thereunder.
	Remark of the Evaluator [XI]	• The firm have revised the label claim from uncoated to film coated tablets along with submission of Rs 5000/- on deposite slip No. 2026317 dated 03.06.2020. The correct label claim is; Each film coated extended release Tablet Contains: Diclofenac Sodium……100mg • Upon clarification for addition of 5% overage the firm replied that they use 5% excess of active material to make their product more effective and stable.
	Decision: Deferred for justification of addition of 5% overage in the formulation.	
381.	Name and address of manufacture / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Joxycycline 100mg Capsule
	Composition	Each Capsule Contains: Doxycycline (as Hyclate)……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7523 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Tetracycline

	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Doxycycline 100mg Capsules MHRA Approved.
	Me-too-status	Medox Capsule 100mg by M/s Maxitech, (Reg#84781)
	GMP Status	The firm was inspected on 18-07-2017 and conclusionof inspection was: Based on areas inspected, documents checked and interaction with the management the firm M/s Jawa Pharmaceuticals Pvt Ltd Lahore was considered to be operating **at the satisfactory level of GMP** compliance as per Drugs, Act, 1976 and rules framed thereunder.
	Remark of the Evaluator [XI]	• Upon clarification for addition of 5% overage the firm replied that they use 5% excess of active material to make their product more effective and stable.
	Decision: Deferred for justification of addition of 5% overage in the formulation.	
382.	Name and address of manufacture / Applicant	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Jincomycin 500mg Capsule
	Composition	Each Capsule Contains: Lincomycin (as HCl)…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7522 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lincocine 500mg Capsule ANSM France approved
	Me-too-status	F-Linco 500mg capsule by M/s Fresh Pharmaceuticals (Reg#080450)
	GMP Status	The firm was inspected on 18-07-2017 and conclusionof inspection was: Based on areas inspected, documents checked and interaction with the management the firm M/s Jawa Pharmaceuticals Pvt Ltd Lahore was considered to be operating **at the satisfactory level of GMP** compliance as per Drugs, Act, 1976 and rules framed thereunder.
	Remark of the Evaluator [XI]	• Upon clarification for addition of 5% overage the firm replied that they use 5% excess of active material to make their product more effective and stable.
	Decision: Deferred for justification of addition of 5% overage in the formulation.	
383.	Name and address of manufacture / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form and Strength	Misal 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5108 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	Amisulpride 50mg Tablets MHRA Approved
	Me-too-status	Amilia 50mg Tablet by M/s Evolution Pharmaceuticals (Reg#101611)
	GMP Status	The firm was inspected on 1-10-2018 and conclusion of inspection was: The firm is found to be complying at a good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as cGMP guidelines per the Drugs Act, 1976, Drap Act 2012 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format. • The firm submitted complete manufacturing outline mentioning all the steps (compression, blistering and packing processes).
	Decision: Approved.	
384.	Name and address of manufacture / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form and Strength	Misal 100mg Tablet
	Composition	Each Tablet Contains: Amisulpride……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5109 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride 100mg Tablets MHRA Approved
	Me-too-status	Amilia 100mg Tablet by M/s Evolution Pharmaceuticals (Reg#101612)
	GMP Status	The firm was inspected on 1-10-2018 and conclusion of inspection was: The firm is found to be complying at a good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as cGMP guidelines per the Drugs Act, 1976, Drap Act 2012 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format. • The firm submitted complete manufacturing outline mentioning all the steps (compression, blistering and packing processes).
	Decision: Approved.	
385.	Name and address of manufacture / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form and Strength	Epezil Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Donepezil HCl…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8142 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anticholinestrase
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	ARICEPT (5mg, 10mg, 23mg) film-coated **USFDA** approved
	Me-too-status	Nepezil 10mg Tablet by M/s Genix Pharma (Reg#083286)
	GMP Status	The firm was inspected on 1-10-2018 and conclusion of inspection was: The firm is found to be complying at a good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as cGMP guidelines per the Drugs Act, 1976, Drap Act 2012 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format. • The firm submitted complete manufacturing outline mentioning all the steps (compression, coating, blistering and packing processes).
	Decision: Approved.	
386.	Name and address of manufacture / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form and Strength	Epezil Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Donepezil HCl.…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8141 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anticholinestrase
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ARICEPT (5mg, 10mg, 23mg) film-coated USFDA approved
	Me-too-status	Nepezil 5mg Tablet by M/s Genix Pharma (Reg#083285)
	GMP Status	The firm was inspected on 1-10-2018 and conclusion of inspection was: The firm is found to be complying at a good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as Cgmp GUIDELINES PER THE Drugs Act, 1976, Drap Act 2012 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format. • The firm submitted complete manufacturing outline mentioning all the steps (compression, coating, blistering and packing processes).
	Decision: Approved.	
387.	Name and address of manufacture / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form and Strength	Empaglu Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8140 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1x14's; As per SRO

	Approval status of product in Reference Regulatory Authorities	JARDIANCE (10mg, 25mg) film-coated tablets USFDA Approved
	Me-too-status	Empoli 10mg Tablet by M/s Sami Pharmaceuticals (Reg#098702)
	GMP Status	The firm was inspected on 1-10-2018 and conclusion of inspection was: The firm is found to be complying at a good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as Cgmp GUIDELINES PER THE Drugs Act, 1976, Drap Act 2012 and rules framed there under.
	Remark of the Evaluator [XI]	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting is required. • The firm submitted undertaking at the end of form 5 duly signed by the technical persons. • The firm submitted complete manufacturing outline mentioning all the steps (compression, coating, blistering and packing processes).
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
388.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Cuflozin Tablet 10mg
	Composition	Each film coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6535 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Farxiga (5mg, 10mg) film coated Tablets USFDA Approved
	Me-too-status	**Xiga 10mg tablets by CCL Pharmaceuticals (Reg#090505)**
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm replied that stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting for the applied product is in process.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
389.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Cuflozin Tablet 5mg
	Composition	Each film coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate.…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6544 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Farxiga (5mg, 10mg) film coated Tablets USFDA Approved
	Me-too-status	Xiga 5mg tablets by CCL Pharmaceuticals (Reg#090504)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm replied that stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting for the applied product is in process.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
390.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Culans 15mg Capsule
	Composition	Each Capsule Contains: Lansoprazole (as Enteric coated pellets 8.5%)……15mg Source of pellets: Vision Pharmaceuticals
	Dairy No. date of R &I fee	Form-5 Dy.No 8897 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lansoprazole 15mg gastro-resistant capsules MHRA Approved
	Me-too-status	Arcozol Capsules 15mg of M/s Pakistan Pharmaceutical (Reg#32239)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm submitted valid GMP certificate of supplier of pellets (vision Pharmaceuticals) along with COA and stability studies data of three batches
	Decision: Approved.	
391.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Culans 30mg Capsule
	Composition	Each Capsule Contains: Lansoprazole (as Enteric coated pellets 22.5%)……30mg Source of pellets: Vision Pharmaceuticals
	Dairy No. date of R &I fee	Form-5 Dy.No 8895 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lansoprazole 30mg gastro-resistant capsules MHRA Approved
	Me-too-status	Arcozol Capsules 30mg of M/s Pakistan Pharmaceutical (Reg#32240)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018

	Remark of the Evaluator [XI]	• The firm submitted valid GMP certificate of supplier of pellets (vision Pharmaceuticals) along with COA and stability studies data of three batches
	Decision: Approved.	
392.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Betalol 5mg Tablet
	Composition	Each Tablet Contains: Nebivolol (as HCl)..…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8892 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too-status	Nebil 5mg Tablets of M/s Getz Pharma Pakistan (Reg.#061345)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm informed that they have submitted SMP (summary of manufacturing procedure) of coated tablet mistakenly and submitted revised SMP of the tablet which doesnot show coating procedure.
	Decision: Approved with innovator's specifications.	
393.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Betalol 10mg Tablet
	Composition	Each Tablet Contains: Nebivolol (as HCl)..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8890 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too-status	Nebil 10mg Tablets Tablets of M/s Getz Pharma Pakistan (Reg.#061346)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm informed that they have submitted SMP of coated tablet mistakenly and submitted revised SMP of the tablet which doesnot show coating procedure.
	Decision: Approved with innovator's specifications.	
394.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Betalol 2.5mg Tablet
	Composition	Each Tablet Contains: Nebivolol (as HCl)……2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8891 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019

	Pharmacological Group	Beta blocking agents, selective
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too-status	Nebil 2.5mg Tablets of M/s Getz Pharma (Reg.#061344)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm informed that they have submitted SMP of coated tablet mistakenly and submitted revised SMP of the tablet which doesnot show coating procedure.
	Decision: Approved with innovator's specifications.	
395.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Cunilor 90mg Tablet
	Composition	Each Film Coated Tablet Contains: Ticagrelor.....90mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6543 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BRILINTA (60mg, 90 mg) film-coated tablet USFDA Approved
	Me-too-status	Virata 90mg tablets **(didn't depict coating)** by M/s CCL Pharmaceuticals (Reg#090349)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm replied that stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting for the applied product is in process.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
396.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Tranmic 500mg Tablet
	Composition	Each Tablet Contains: Tranexamic Acid.....500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6539 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antifibrinolytics
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tranexamic Acid 500mg coated tablet MHRA Approved
	Me-too-status	Traumax Tablet 500mg of M/s Siza International (Reg. #024787)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018

	Remark of the Evaluator [XI]	• The firm has claimed manufacturer's specifications but the official monograph is available in BP. • The firm informed that they have submitted SMP of coated tablet mistakenly and submitted revised SMP of the tablet which doesnot show coating procedure.
	Decision: Approved.	
397.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Ketafast 50mg/ml Injection
	Composition	Each ml contains: Ketamine (as HCl)..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8902 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	General Anesthesic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketalar 50mg/ml Injection, of MHRA approved
	Me-too-status	Ketalite Injection 50mg/ml by M/s Elite Pharmaceuticals (Reg#62893)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
398.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Ketafast 10mg/ml Injection
	Composition	Each ml contains: Ketamine (as HCl)..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8893 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	General Anesthesic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketalar 10mg/ml Injection, of MHRA approved
	Me-too-status	KANOX INJECTION 10mg/ml by M/s **Duo Pharma** Reg#21996)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
399.	Name and address of manufacture / Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Bud-Air Dry Powder Inhalation 400/12mcg capsule
	Composition	Each DPI Capsule Contains: Budesonide……400mcg Formoterol fumarate dihydrate……12mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 6564 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Glucocorticosteroid/Selective β2 adrenoceptor agonist
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort Turbohaler 400micrograms/12micrograms/inhalation, inhalation powder (MHRA approved)
	Me-too-status	Formiget DPI Capsule 400mcg+12mcg by Getz Pharma (Reg#098828)
	GMP Status	The firm was inspected on 17-01-2019 and conlusion of inspection was: Grant of Section/ Facility and Regularization.

Remark of the Evaluator [XI]

Remarks	**Response by the firm**
• As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.	The firm submitted approved layout plan for manufacturing of DPI but have no approved section/manufacturing facility at present. Moreover the firm submitted a list of equipments that will be used in manufacturing including eqipments for DPI mixing, DPI filling, capsule polishing, blistering and packaging. **(No evidence of availability)**
• As per 290th decision of Registration board, provide evidence of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia.	The firm submitted list of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" **(No evidence of availability)**
• The reference formulation have mentioned the hydrated form (dihydrate) of Formoterol fumarate in the label claim while you have not mentioned the hydrated form. Revise the label claim as per reference formulation mentioning the hydrated form along with submission of applicable fee.	The firm have revised the label claim mentioning the hydrated form of Formoterol fumarate in the label claim
• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.	The firm have submitted commitment for performing the stability study as per Requirements of Registration Board decision of 293rd meeting.

Decision: Deferred for confirmation of required manufacturing facility "Dry Powder inhaler" section with manufacturing and testing equiments for applied formulation.

400.	Name and address of manufacture / Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Remet 50mg Tablet
	Composition	Each film coated Tablet Contains: Vildagliptin……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8797 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5
	Finished product specifications	In-house
	Pack size and Demand Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUS vildagliptin 50mg tablets TGA Approved

	Me-too-status	Gevo 50mg Tablets by M/s BJ Pharmaceuticals, (Reg#82780)
	GMP Status	The firm was inspected on 17-01-2019 and conlusion of inspection was: Grant of Section/ Facility and Regularization.
	Remark of the Evaluator [XI]	• The firm submitted revised label claim and master formulation along with submission of Rs 20000/- on deposit slip No. 2029286 dated 09.06.2020. The correct label claim is as under: Each Tablet Contains: Vildagliptin……50mg
	Decision: Approved with innovator's specifications and following label claim: **Each Tablet Contains:** **Vildagliptin……50mg**	
401.	Name and address of manufacture / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Wilsonide Plus Dry Powder Inhaler 400/12 mcg capsule
	Composition	Each DPI Capsule Contains: Budesonide…….400mcg Formoterol fumarate dihydrate…….12mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 6952 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Glucocorticosteroid/Selective β2 adrenoceptor agonist
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort Turbohaler 400micrograms/12micrograms/inhalation, inhalation powder (MHRA approved)
	Me-too-status	Formiget DPI Capsule 400mcg+12mcg by Getz Pharma (Reg#098828)
	GMP Status	The firm was inspected on 24-01-2018 and conclusion of inspection was: "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."

Remark of the Evaluator [XI]

Remarks	**Response by the firm**
• As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.	The firm submitted approved layout plan for manufacturing of DPI and panel constituted letter for onsite inspection but have no approved section/manufacturing facility at present. Moreover the firm submitted a list of equipments that will be used in manufacturing including eqipments for DPI mixing and DPI filling.
• As per 290th decision of Registration board, provide evidence of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia.	The firm informed that equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" have been procured and are available for testing.

	• The reference formulation have mentioned the hydrated form (dihydrate) of Formoterol fumarate in the label claim while you have not mentioned the hydrated form. Revise the label claim as per reference formulation mentioning the hydrated form along with submission of applicable fee.	The firm have revised the label claim mentioning the hydrated form of Formoterol fumarate in the label claim
	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.	The firm have submitted commitment for performing the stability study as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder inhaler" section with manufacturing and testing equiments for applied formulation.	
402.	Name and address of manufacture / Applicant	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Ledisuvir Tablets 400mg/90mg
	Composition	Each Film Coated Tablet Contains: Sofosbuvir…..…400mg Ledipasvir……....90mg
	Dairy No. date of R &I fee	Form-5D Dy.No 8813 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-Viral
	Type of form	Form 5-D
	Finished product specifications	Manufacturer 's Specifications
	Pack size and Demand Price	28's; As per SRO
	Approval status =of product in Reference Regulatory Authorities	Harvoni 90mg/400mg film coated tablets, US-FDA Approved
	Me-too-status	Sofopas 90mg/400mg Tablet by M/s Genix Pharma (Reg#82274)
	GMP Status	The firm was inspected on 22/02/2018 and Recommendations of inspections was: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and findings during inspection, M/s pacific pharma ltd Multan road Lahore, was considered to be operating at good level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends considering the firm for grant of GMP certificate for export purposes. "GMP Certificate Issued on 05-03-2018."
	Remark of the Evaluator [XI]	• You have applied on form 5-D. Please apply on correct form • Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
403.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Artinium Injection 80mg/ml I/M
	Composition	Each ml contains: Artemether ……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8490 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- malarial
	Type of form	Form 5

	Finished product specifications	IP
	Pack size and Demand Price	1mlx6's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Artemether solution for injection 80mg/ml WHO Approved formulation
	Me-too-status	Artegen 80mg Injection of M/s Fassgen Pharma (Reg#56462)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format. • The manufacturer have claimed IP specifications while official monograph is not available in any pharmacopeia (USP, BP, IP, JP). • The firm has provided liquid ampoule section confirmed from GMP certificate.
	Decision: Approved.	
404.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Tazolin Injection 2.25gm
	Composition	Each Vial Contains: Piperacillin sodium eq to Piperacillin…..2gm Tazobactam sodium eq to tazobactam…..0.25gm
	Dairy No. date of R &I fee	Form-5 Dy.No 8493 dated 26-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's with WFI; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tanzo Injection by M/s Bosch Pharmaceutical (Reg. No. 39593)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	• The firm submitted that lyophilized powder for injection was written on the label by mistake and submitted the revised the label accordingly.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	

405.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Tazolin Injection 4.5gm
	Composition	Each Vial Contains: Piperacillin sodium eq to Piperacillin…..4gm Tazobactam sodium eq to tazobactam…..0.5gm
	Dairy No. date of R &I fee	Form-5 Dy.No 8494 dated 26-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's with WFI; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tacip 4.5gm Injection by M/s Macter Int. (Reg#73632)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	• The firm submitted that lyophilized powder for injection was written on the label by mistake and submitted the revised the label accordingly.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	
406.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Augmoxin Injection 1.2gm
	Composition	Each Vial Contains: Amoxicillin sodium eq to Amoxicillin…1000mg Potassium Clavulanate eq to Clavulanic Acid…200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8492 dated 26-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Augmentin Intravenous (1000 mg/200 mg powder for solution for injection/infusion) MHRA Approved
	Me-too-status	Stamentin Dry Powder Injection 1.2gm by M/s Stallion Pharmaceuticals (Reg. No. 77234)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a

		satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	
407.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Augmoxin Injection 600mg
	Composition	Each Vial Contains: Amoxicillin sodium eq to Amoxicillin……500mg Potassium Clavulanate eq to Clavulanic Acid…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8491 dated 26-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Augmentin Intravenous (500 mg/100 mg powder for solution for injection/infusion) MHRA Approved
	Me-too-status	Stamentin Dry Powder Injection 600mg by M/s Stallion Pharmaceuticals (Reg. No. 77233)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	
408.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Floxin Injection 250mg
	Composition	Each Vial Contains: Flucloxacillin as Sodium.…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8487 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Beta-lactamase resistant penicillins
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flucloxacillin 250 mg, powder for solution for injection MHRA Approved
	Me-too-status	Fluclox 500mg Dry Powder Injection by M/s Stallion Pharmaceuticals (Reg. No. 78878)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems.

		Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	
409.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Floxin Injection 500mg
	Composition	Each Vial Contains: Flucloxacillin as Sodium……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8486 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Beta-lactamase resistant penicillins
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flucloxacillin 500mg, powder for solution for injection MHRA Approved
	Me-too-status	Fluclox 500mg Dry Powder Injection by M/s Stallion Pharmaceuticals (Reg. No. 78878)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder injectable (Penicillin)" section for applied formulation.	
410.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Proket Injection 250mg/5ml
	Composition	Each ml contains: Ketamine as HCl…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8488 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	General anaesthetic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	5mlx5ampoules; As per SRO
	Approval status of product in Reference Regulatory Authorities	KETAMINE INTERPHARMA ketamine (as hydrochloride) 250mg/5mL solution for injection ampoule TGA Approved
	Me-too-status	Ketwim 250mg/5ml Injection by M/s Wimits Pharmaceuticals (Reg# 085112)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previoud inspection had

		been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format. • The firm submitted that they have applied for single volume 5ml and 2ml was typographic error. • The firm submitted another evidence of applied formulation in TGA Austrailia in the same volume and packed in ampoule. The firm revised the label claim as: Each 5ml ampoule contains: Ketamine HCl eq. to ketamine base……..250mg
	Decision: Deferred for submission of fee for revision of label claim of applied formulation.	
411.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Phenra-Vil Injection 45.5mg/2ml
	Composition	Each 2ml ampoule contains: Pheniramine Maleate.…45.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8495 dated 26-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Anti-Histamine
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2mlx50's; 2mlx100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Zafvil Injection of Zafa Pharmaceuticals (Reg#030637)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previous inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
412.	Name and address of manufacture / Applicant	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Dolnot Plus Injection
	Composition	Each 2ml contains: Diclofenac sodium……75mg Lidocaine HCl……..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8489 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	NSAID/ Local anaesthetic
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2mlx10 ampoule; As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac-Mepha 75 ampoules for injection of (Swiss medics approved)
	Me-too-status	Aram Plus Injections of M/s Bosch Pharmaceuticals (Reg#048488)
	GMP Status	Last inspection was conducted on 10-02-2020 and conclusion of inspection was: Base on the findings of the inspection, it is concluded that most of the shortcomings of the previous inspection had been rectified. As the GMP is a continuous process, firm was advised to make further improvements in their systems. Based upon the visit of the facility, documents reviewed and people met, the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Remark of the Evaluator [XI]	•
	Decision: Approved with innovator's specifications.	
413.	Name and address of manufacture / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name + Dosage Form and Strength	Revosirox Tablet 400mg
	Composition	Each dispersible tablet contains: Deferasirox.…400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8800 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Iron chelating agent
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	**Asunra Orodispersible tablets 400mg Novartis (Bangladesh) Ltd**
	Me-too-status	Dasirox Tablet 400mg by M/s CCL Phamaceuticals (Reg#68113)
	GMP Status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory • The firm provided evidence of approval of applied formulation not in reference regulatory authorities / agencies which could not be verified
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	
414.	Name and address of manufacture / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name + Dosage Form and Strength	Revosirox Tablet 100mg
	Composition	Each dispersible tablet contains: Deferasirox……100mg

	Dairy No. date of R &I fee	Form-5 Dy.No 8799 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Iron chelating agent
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	**Asunra Orodispersible tablets 100mg Novartis (Bangladesh) Ltd**
	Me-too-status	Dasirox Tablet 100mg by M/s CCL Phamaceuticals (Reg#68112)
	GMP Status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory • The firm provided evidence of approval of applied formulation not in reference regulatory authorities / agencies and which could not be verified
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	
415.	Name and address of manufacture / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name + Dosage Form and Strength	Evergraf 0.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Everolimus…..0.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7575 dated 21-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Selective Immuno- suppressant
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZORTRESS (0.25 mg, 0.5 mg, 0.75 mg) (uncoated) tablets USFDA Approved
	Me-too-status	Everglo 0.5mg tablet by M/s Global Pharmaceuticals (Reg#096504)
	GMP Status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory. • The firm revised the label claim from film coated tablet to uncoated tablet along with submission of Rs. 5000/- on deposite slip No, 0805589 date 15.06.2020. The revised label claim is as under: Each Tablet Contains: Everolimus…..0.5mg Moreover the firm submitted revised master formulation.

	Decision: Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	
416.	Name and address of manufacture / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name + Dosage Form and Strength	Servigraf gastro-resistant Tablet 180mg
	Composition	Each gastro-resistant tablet contains: Mycophenolic Acid.....…180mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7832 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Selective Immuno- suppressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mycophenolic acid 180mg gastro-resistant tablets (MHRA Approved)
	Me-too-status	Myfortic 180mg Gastro-Resistant Tablet by M/s Novartis Pharma (Reg# 033172)
	GMP Status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory • The firm have mentioned the salt form in label claim along with submission of Rs. 5000/- on deposite slip No. 0805590 date 15.06.2020. The revised label claim is as under: Each enteric coated tablet contains: Mycophenolate sodium equivalent to Mycophenolic Acid…...…180mg
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	
417.	Name and address of manufacture / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name + Dosage Form and Strength	Servigraf gastro-resistant Tablet 360mg
	Composition	Each gastro-resistant tablet contains: Mycophenolic Acid..…360mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7833 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Selective Immuno- suppressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mycophenolic acid 360mg gastro-resistant tablets (MHRA Approved)
	Me-too-status	Myfortic 360mg Gastro-Resistant Tablet by M/s Novartis Pharma (Reg# 033173)

	GMP Status	The firm was inspected on 02-07-2019 and conclusion of inspection was: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory • The firm have mentioned the salt form in label claim along with submission of Rs. 5000/- on deposite slip No. 0805591 date 15.06.2020. The revised label claim is as under: Each enteric coated tablet contains: Mycophenolate sodium equivalent to Mycophenolic Acid…..…360mg
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs	
418.	Name and address of manufacture / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Tramol 50mg Capsule
	Composition	Each Capsule Contains: Tramadol HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7954 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Opioid Analgesic
	Type of form	Form 5
	Finished product specifications	**BP**
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol Hydrochloride Capsules 50mg MHRA Approved
	Me-too-status	Palmadol Capsule 50 mg by M/s Palpex Pharmaceuticals (Reg #82942)
	GMP Status	GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved format.
	Decision: Approved.	
419.	Name and address of manufacture / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Meberin 200mg Capsule
	Composition	Each modified release Capsule Contains: Mebeverine HCl (SR pellets 50%)……200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7960 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Anticholinergic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Colofac MR Modified release capsule (MHRA Approved)
	Me-too-status	Mebever MR 200mg Capsule of M/s Getz Pharma (Reg.#050747)

	GMP Status	GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved format. • The firm provided source of pellets (Vision Pharma), certificate of analysis of pellets, stability studies data of three batches and GMP certificate of supplier of pellets
	Decision: Approved with innovator's specifications.	
420.	Name and address of manufacture / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Diclomed 100mg SR Capsule
	Composition	Each Capsule Contains: Diclofenac sodium (as sustained release pellets 32%) …….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7959 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclomax Retard 100mg capsule MHRA Approved
	Me-too-status	Dicloyan-S 100mg capsule Roryan Pharmaceutical (Reg.#68337)
	GMP Status	GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved format. • The firm provided source of pellets (Vision Pharma), certificate of analysis of pellets, stability studies data of three batches and GMP certificate of supplier of pellets
	Decision: Approved.	
421.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-4/1, A&B Block-21, Federal B industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Irozaf FA Chewable tablet 100mg/0.35mg
	Composition	Each chewable tablet contains: Iron as Iron (III) Hydroxide Polymaltose complex…..…100mg Folic Acid……0.35mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4924 dated 04-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Iron in combination with folic acid
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferrum Fol 100mg/350microgram chewable tablet France Approved… as provided by the firm could not be verified
	Me-too-status	Inofer-F Chewable Tablet by Kaizen Pharmaceuticals (Reg#81171)
	GMP Status	"GMP certificate Issued on 15-5-2018 based on inspection conducted on 11-1-2018."
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format along with undertaking at the end of form 5 signed by the technical persons

		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting could not be verified
	Decision: Approved with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
422.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-4/1, A&B Block-21, Federal B industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Irozaf Chewable tablet 100mg
	Composition	Each chewable tablet contains: Iron as Iron (III) Hydroxide Polymaltose complex…...100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4925 dated 04-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Anti-anemic preparations
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferrum Hausmann100mg chewable tablet France Approved… as provided by the firm could not be verified
	Me-too-status	Rubifer-F Chewable Tablets by M/s Ali Gohar Pharmaceuticals (Reg#28121)
	GMP Status	"GMP certificate Issued on 15-5-2018 based on inspection conducted on 11-1-2018."
	Remark of the Evaluator [XI]	• The firm revise the 1st page of form 5 as per approved format. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting could not be verified
	Decision: Approved with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
423.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-4/1, A&B Block-21, Federal B industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Irozaf Drops 50mg/ml
	Composition	Each ml contains: Iron as Iron (III) Hydroxide Polymaltose complex…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3944 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Anti-anemic preparations
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	15ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	MALTOFER Drops 50mg/mL TGA Approved
	Me-too-status	Feritose Drops by M/s Libra Pharmaceuticals (Reg#77452)
	GMP Status	"GMP certificate Issued on 15-5-2018 based on inspection conducted on 11-1-2018."
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format.
	Decision: Approved with innovator's specifications.	
424.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Vomidox Tablet 10mg/10mg

	Composition	Each enteric coated tablet contains: Doxylamine succinate……10mg Pyridoxine…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5335 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihistamines
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	DICLEGIS (doxylamine succinate/pyridoxine hydrochloride 10/10mg) film coated delayed release tablet USFDA approved
	Me-too-status	Omit 10/10mg Tablet by M/s Scilife Pharma, (Reg#082087)
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	• The firm submitted revised Form 5 and corrected the salt form pyridoxine hydrochloride instead of pyridoxine in the label claim without submission of fee. The firm futher stated that mentioning pyridoxine instead of pyridoxine hydrochloride was a typographical mistake and that they have applied pyridoxine hydrochloride in master formulation
	Decision: Deferred for submission of applicable fee for revision of formulation.	
425.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glifloz-M 5mg/500mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……5mg Metformin HCl……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7564 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Manufacturer's specifications
	Finished product specifications	14's; As per SRO
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5 mg/500 mg, 12.5mg/1000 mg) film coated tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	• The firm did not provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm

		• The firm informed that stability studies of the above product is in process and data of three batches will be submitted upon completion of the study.
	Decision: Deferred for following: **Submission of application on form-5D alongwith differential fee.** **submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
426.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Inoset 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sertraline HCl…..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 71 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LUSTRAL 50mg film coated tablets MHRA Approved
	Me-too-status	Seralin 50mg Tablet by M/s Bosch Pharmaceuticals (Reg#83323)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator XI	• The firm have revised the label claim as per reference formulation not considering the salt factor along with submission of Rs. 20,000/- on deposit slip No.2044519 dated 04-06-2020. The revised label claim is: Each Film Coated Tablet Contains: Sertraline HCl equivalent to Sertraline…….…50mg
	Decision: Approved.	
427.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Inopride 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride hydrochloride…..…50mg
	Dairy No. date of R &I fee	Dy. No 83 dated 01-01-2019, Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Propulsives
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 50mg tablet (PMDA) Japan Approved
	Me-too-status	Xepride tablet 50mg of M/s Usawa Pharmaceuticals (Reg. # 076818)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator XI	• The firm revised the weight of API in master formulation as per reference formulation along with submission of Rs.

		5000/- on deposit slip No. 2044517 dated 04-06-2020. The weight of API mentioned in master formulation was 160mg/tab while weight of API in tab is 50mg/tab. The firm was not asked for submission of fee. • The manufacturer has claimed manufacturer's specifications while official monograph is not available in any pharmacopeia (USP, BP, IP, JP).
	Decision: Approved with innovator's specifications.	
428.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Moxiventor 400mg tablet
	Composition	Each Film Coated Tablet Contains: Moxifloxacin HCl……...400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 81 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Quinolone antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVELOX 400mg tablets, film-coated. USFDA approved
	Me-too-status	Moxizyan 400mg Tablets, film-coated by Genesis Pharmaceuticals (Reg# 77252)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have revised the label claim as per reference formulation not considering the salt factor along with submission of Rs. 5000/- on deposite slip No.2044521 dated 04-06-2020. The revised label claim is: Each Film Coated Tablet Contains: Moxifloxacin as HCl…...…400mg • The manufacturer have claimed innovator's specifications while official monograph available in USP.
	Decision: Approved with innovator's specifications.	
429.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Innocid 500mg/5ml Injection
	Composition	Each 5ml ampoule contains: Tranexamic Acid…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 76 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antifibrinolytics
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRANEXAMIC ACID 500mg/5 mL solution for injection ampoule TGA approved
	Me-too-status	Tremic -500 Injection by M/s Fynk Pharmaceuticals (Reg#62678)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was:

		Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation along with submission of Rs. 5000/- on deposit slip No.2044520 date 04-06-2020 but did not address the following short comings. • You have applied for tranexamic acid injection but in master formulation tranexamic acid hydrochloride is mentioned, clarify? • Furthermore, master formulation is not as per reference formulation justify (Having no pH adjusting agents hydrochloric acid, sodium hydroxide)?
	Decision: Deferred for revision of formulation as per reference product.	
430.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Irazem tablet 20mg
	Composition	Each Tablet Contains: Aripiprazole……20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10821 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify (2mg, 5mg, 10mg, 15mg, 20mg, 30mg) Tablets USFDA Approved
	Me-too-status	Apify 20mg Tablet by M/s Akhai Pharma (Reg#76248)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
431.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Irazem tablet 10mg
	Composition	Each Tablet Contains: Aripiprazole……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10819 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify (2mg, 5mg, 10mg, 15mg, 20mg, 30mg) Tablets USFDA Approved
	Me-too-status	Apify 10mg Tablet by M/s Akhai Pharma (Reg#76246)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory.
	Decision: Approved.	

432.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Irazem tablet 15mg
	Composition	Each Tablet Contains: Aripiprazole……15mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10820 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify (2mg, 5mg, 10mg, 15mg, 20mg, 30mg) Tablets USFDA Approved
	Me-too-status	Apify 15mg Tablet by M/s Akhai Pharma (Reg#76247)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory.
	Decision: Approved.	
433.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Irazem tablet 30mg
	Composition	Each Tablet Contains: Aripiprazole……30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10822dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify (2mg, 5mg, 10mg, 15mg, 20mg, 30mg) Tablets USFDA Approved
	Me-too-status	Apify 30mg Tablet by M/s Akhai Pharma (Reg#76249)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
434.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Imuprine Tablet 50mg
	Composition	Each Tablet Contains: Azathioprine…….50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10823 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Other immunosuppressants
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azafalk 50mg film-coated tablets (MHRA Approved)

	Me-too-status	Azoprine Tablets by M/s Global Pharmaceuticals (Reg#25196)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm have revised the label claim from uncoated to film coated tablet along with submission of Rs 5000/- on deposite slip No. 2048060 dated 23-07-2020. The firm also revised the master formulation and manufacturing method. The revise label claim is: Each film coated Tablet Contains: Azathioprine…….50mg • The firm revised the 1st page of form 5 as per approved format
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
435.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mygaba Capsule 100mg
	Composition	Each Capsule Contains: Gabapentin……..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10802 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 100mg capsule (MHRA Approved)
	Me-too-status	Gabateric 100 mg Capsule by M/s High-Q Pharmaceutical (Reg#47245)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
436.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mygaba Capsule 300mg
	Composition	Each Capsule Contains: Gabapentin…..…300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10803 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 300mg capsule (MHRA Approved)
	Me-too-status	Gabateric 300 mg Capsule by M/s High-Q Pharmaceutical (Reg#47341)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant

	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
437.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mygaba Capsule 400mg
	Composition	Each Capsule Contains: Gabapentin…….400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10804 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 400mg capsule (MHRA Approved)
	Me-too-status	Gabateric 400 mg Capsule by M/s High-Q Pharmaceutical (Reg#47246)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
438.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Hirafen Tablet 400mg
	Composition	Each film coated tablet contains: Ibuprofen……..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10814 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen 400mg film coated tablet (MHRA approved)
	Me-too-status	Medibrufen 400mg tablet by M/s Mediate Pharma (Reg#61940) (does not depict coating)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
439.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Hirafen Tablet 200mg
	Composition	Each film coated tablet contains: Ibuprofen……..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10813 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID

	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen 200mg film coated tablets (MHRA Approved)
	Me-too-status	Medibrufen 200mg tablet by M/s Mediate Pharma (Reg#61941) (does not depict coating)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
440.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Hirafen Suspension 100mg/5ml
	Composition	Each 5ml contains: Ibuprofen……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10816 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen 100mg/5ml Suspension (MHRA Approved)
	Me-too-status	Nuprin 100mg Suspension by M/s Reign Pharma (Reg#76477)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
441.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Hirafen Tablet 600mg
	Composition	Each film coated tablet contains: Ibuprofen……..600mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10815 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen 600mg film coated tablets (MHRA approved)
	Me-too-status	Fenbru 600mg Tablets by M/s Platinum pharma (Reg#42105)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	

442.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Sykopride Tablet 50mg
	Composition	Each Tablet Contains: Levosulpiride……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10800 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 50mg tablets AIFA Italy Approved.
	Me-too-status	Sulvoric 50mg Tablet by M/s High-Q (Reg#070485)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
443.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Sykopride Tablet 25mg
	Composition	Each Tablet Contains: Levosulpiride……..…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10799 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	Me-too-status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
444.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Sykopride Tablet 100mg
	Composition	Each Tablet Contains: Levosulpiride…...…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10801 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 100mg tablets, AIFA Italy approved.

	Me-too-status	Sulvoric 100mg Tablet by M/s High-Q (Reg#070486)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
445.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Melican Tablet 15mg
	Composition	Each Tablet Contains: Meloxicam……..…15mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10812 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Non-steroidal anti-inflammatory drugs (NSAIDs)
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MOBIC (7.5mg, 15mg) uncoated Tablets USFDA Approved
	Me-too-status	Melflam 15mg Tablets by M/s Aries Pharmaceuticals (Reg#84266)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
446.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Melican Tablet 7.5mg
	Composition	Each Tablet Contains: Meloxicam……7.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10811 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Non-steroidal anti-inflammatory drugs (NSAIDs)
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MOBIC (7.5mg, 15mg) uncoated Tablets USFDA Approved
	Me-too-status	Melflam 7.5mg Tablets by M/s Aries Pharmaceuticals (Reg#84265)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved.	
447.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 10mg
	Composition	Each Tablet Contains: Methotrexate……..10mg

	Dairy No. date of R &I fee	Form-5 Dy.No 10798 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants WHO ATC code: L04AX03
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 10mg tablets MHRA Approved
	Me-too-status	Methotrexate tablet 10mg of M/s Pak China International (Reg# 066009)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	
448.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mexate Tablet 2.5mg
	Composition	Each Tablet Contains: Methotrexate…….2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10797 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other immunosuppressants
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Methotrexate 2.5mg Tablets MHRA Approved
	Me-too-status	Methotrexate 2.5mg by PAK CHINA INTERNATIONAL (Reg #066007)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Decision: Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	
449.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 300mg
	Composition	Each Capsule Contains: Pregabalin…….300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10810 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved

	Me-too-status	Gabica 300mg Capsules by M/s Getz Pharma (Reg#47368)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
450.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 200mg
	Composition	Each Capsule Contains: Pregabalin……..…200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10809 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 200mg Capsules by M/s Getz Pharma (Reg#47367)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
451.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 100mg
	Composition	Each Capsule Contains: Pregabalin……..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10807 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 100mg Capsules by M/s Getz Pharma (Reg#47366)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory.
	Decision: Approved with innovator's specifications.	
452.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 150mg
	Composition	Each Capsule Contains: Pregabalin……150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10808 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019

	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 150mg Capsules by M/s Getz Pharma (Reg#48724)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
453.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 50mg
	Composition	Each Capsule Contains: Pregabalin……..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10805 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 50mg Capsules by M/s Getz Pharma (Reg#48725)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format
	Decision: Approved with innovator's specifications.	
454.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Gylica Capsule 75mg
	Composition	Each Capsule Contains: Pregabalin……75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10806 dated 05-03-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 75mg Capsules by M/s Getz Pharma (Reg#47365)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format duly signed by the signatory
	Decision: Approved with innovator's specifications.	
455.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan

	Brand Name + Dosage Form and Strength	Ultradol Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10817 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Opioid analgesic
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ULTRAM (50mg) film tablets, USFDA Approved.
	Me-too-status	Allay 50mg Tablet by M/s Tabros Pharma (Reg#74963)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved format alongwith undertaking at the end of form 5 signed by the technical persons
	Decision: Approved.	
456.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Alavert-D Tablet 5/120mg
	Composition	Each film coated extended-release tablet contains: Loratadine …….....5mg Pseudoephedrine Sulfate ……...120mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10936 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Sympathomimetics (Nasal Decongestants)
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Claritin-D (5mg;120mg) Extended Release tablets USFDA Approved
	Me-too-status	Softin- P tablet of M/s Werrick Pharma (Reg. # 060094) Could not be confirmed as extended- release tablet
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format but submitted without applicant signature. • The firm submitted revised form 5 and revised the label claim from bilayered tablet to film coated extended release tablet along with submission of Rs. 5000/- on deposit slip No. 2048070 dated 29.07.2020. The also submitted revised master formulation and manufacturing outline. • However, the reference formulation contains contains 5 mg loratadine in the tablet coating (immediate release) and 120mg pseudoephedrine sulfate equally distributed between the tablet coating (immediate release) and the barrier-coated core (extended release). The two active components in the coating are quickly liberated; release of the decongestant in the core is delayed for several hours. • The manufacturing method of the applied product is not as per reference formulation

	Decision: Deferred for submission of manufacturing outline as per reference formulation.	
457.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Ultradol SR Tablet 100mg
	Composition	Each film coated sustained release Tablet Contains: Tramadol HCl…….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10818 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Opioid analgesic
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brimisol PR 100mg prolonged release tablets MHRA Approved
	Me-too-status	Zultra SR 100mg tablet by M/s Wilshire Laboratories (Reg#80713)
	GMP Status	The firm was inspected on 29-01-2019 and was overall GMP compliant
	Remark of the Evaluator [XI]	• The firm did not revised the 1st page of form 5 as per prescribed format and also submitted without applicant signature. • The firm submitted revised form 5 and revised the label claim from immediate release tablet to film coated sustained release tablet along with submission of Rs. 5000/- on deposit slip No. 2048069 dated 29.07.2020. The also submitted revised master formulation and manufacturing outline.
	Decision: Deferred for submission of differential fee of Rs. 15,000 for revision of formulation.	
458.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 10/40mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…10mg Telmisartan…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41200 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 10mg/40mg (USFDA Approved)
	Me-too-status	Amtas 10mg + 40mg Tablet of M/s Sami Pharmaceuticals (Reg. # 066945)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Evidence of availability of bilayered compression tablet facility

		• Master formulation is missing
	Decision: Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.	
459.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 5/80mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..5mg Telmisartan……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41202 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 5mg/80mg (USFDA Approved)
	Me-too-status	Telmipin 5mg + 80mg Tablet of M/s Schazoo Zaka (Reg. # 0090511)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Decision: Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.	
460.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 5/40mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..5mg Telmisartan…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41201 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 5mg/40mg (USFDA Approved)
	Me-too-status	Telmipin 5mg + 40mg Tablet of M/s Schazoo Zaka (Reg. # 0090514)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level

		of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 and undertaking is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Decision: Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.	
461.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 10/80mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..10mg Telmisartan…..80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41199 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 10mg/80mg (USFDA Approved)
	Me-too-status	Telmipin 10mg + 80mg Tablet of M/s Schazoo Zaka (Reg. # 0090512)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Decision: Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.	
462.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Treclin Gel 1%/0.025%
	Composition	Each gram contains: Clindamycin phospate eq to Clindamycin…….10mg Tretinoin…….0.25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8523 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antibiotic, Retinoids
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Treclin 1 % / 0.025 % (Clindamycin/Tretinoin) w/w gel (MHRA Approved)
	Me-too-status	

	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm provide evidence of Acdermin Gel 1.2%w/w / 0.025%w/w by M/s Atco Laboratories (Reg#58435) having different concentration of API from the applied product. • The firm revised the type of primary packaging container from plastic laminated tube to aluminium tube with an epoxyphenolic internal lacquer, fitted with a polyethylene cap as per reference product
	Decision: Deferred for revision of formulation as per reference product.	
463.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Nicotab 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Nicorandil……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8524 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 10mg tablet un-coated. TGA approved
	Me-too-status	Nicogina 10mg Tablet by M/s Macter International (Reg. No. 67049)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have revised the label claim from film coated tablet to uncoated tablet along with submission of Rs 5000/- on deposite slip No. 1996023 dated 27-07-2020. The firm also revised the master formulation and manufacturing method. The revise label claim is: Each uncoated Tablet Contains: Nicorandil …….10mg
	Decision: Approved.	
464.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Nicotab 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Nicorandil……20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8525 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019

	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 20mg un-coated tablet. TGA approved
	Me-too-status	Nicogina 20mg Tablet by M/s Macter International (Reg. No. 67050)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have revised the label claim from film coated tablet to uncoated tablet along with submission of Rs 5000/- on deposit slip No. 1996024 dated 27-07-2020. The firm also revised the master formulation and manufacturing method. The revise label claim is: Each uncoated Tablet Contains: Nicorandil …….20mg
	Decision: Approved.	
465.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Olmetab-A 5/20mg Tablet
	Composition	Each Tablet Contains: Amlodipine Besylate…5mg Olmesartan Medoxomil…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8266 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/20mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/20mg of M/s Searle Pakistan (Reg#076187)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 revising the label claim from uncoated to film coated tablets and corrected the salt form of amlodipine along with submission of Rs. 5000/- on deposite slip No. 1996019 dated 06.08.2020. The correct label claim is: Each film coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……..5mg Olmesartan Medoxomil……..…20mg
	Decision: Approved with innovator's specifications.	

466.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Olmetab-A 5/40mg Tablet
	Composition	Each Tablet Contains: Amlodipine Besylate…5mg Olmesartan Medoxomil…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8267 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/40mg of M/s Searle Pakistan (Reg#076188)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 revising the label claim from uncoated to film coated tablets and corrected the salt form of amlodipine along with submission of Rs. 5000/- on deposite slip No. 1996020 dated 06.08.2020. The correct label claim is: Each film coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine…….5mg Olmesartan Medoxomil…….40mg
	Decision: Approved with innovator's specifications.	
467.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Olmetab-A 10/20mg Tablet
	Composition	Each Tablet Contains: Amlodipine Besylate…10mg Olmesartan Medoxomil…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8268 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/20mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 10/20mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based

		on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 revising the label claim from uncoated to film coated tablets and corrected the salt form of amlodipine along with submission of Rs. 5000/- on deposite slip No. 1996021 dated 06.08.2020. The correct label claim is: Each film coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……..10mg Olmesartan Medoxomil……..…20mg
	Decision: Approved with innovator's specifications.	
468.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name + Dosage Form and Strength	Olmetab-A 10/40mg Tablet
	Composition	Each Tablet Contains: Amlodipine Besylate…10mg Olmesartan Medoxomil…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8269 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 10/40mg by M/s Searle Pakistan (Reg#076190)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted revised form 5 revising the label claim from uncoated to film coated tablets and corrected the salt form of amlodipine along with submission of Rs. 5000/- on deposite slip No. 1996022 dated 06.08.2020. The correct label claim is: Each film coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……..10mg Olmesartan Medoxomil……..…40mg
	Decision: Approved with innovator's specifications.	
469.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Simzet 10/40mg Tablet
	Composition	Each film coated Tablet Contains: Ezetimibe……10mg Simvastatin……..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10434 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Lipid lowering agent/HMG-CoA reductase inhibitor
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications

	Pack size and Demand Price	7's, 10's, 14's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN (ezetimibe and simvastatin) (10/10, 10/20, 10/40, 10/80) tablets USFDA Approved
	Me-too-status	Simbex tablet 10/40 by M/s Searle Pharma (Reg#44050)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation (but reference formulation is uncoated). • The chemistry review Vytorin of USFDA states that in solid state, oxidation of simvastatin can occur, especially at elevated temperature, therefore, butylated hydroxyanisole is added to the drug substance. Butylated hydroxyanisole NF, citric acid monohydrate USP, and propyl gallate NF. • Hence, based on the information extracted from Public assessment report it is concluded that simvastatin losses to thermal degradation in the presence of oxygen, antioxidants shall be added in the formulation. These antioxidants shall also be quantified by suitable test method. The manufacturing of the applied formulation should also be as per innovator that involves the following steps: a) sifting of the main excipients b) preparation of the drug dispersion c) top spray granulation and drying d) spraying of the antioxidants solution on the granules, e) dry screening, f) blending and lubrication g) compression Moreover, the shelf life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. As Zone IV A is more severe condition the shelf life will be more stringent.
	Decision: Approved with innovator's specifications.	
470.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Simzet 10/20mg Tablet
	Composition	Each film coated Tablet Contains: Ezetimibe……10mg Simvastatin……..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10435 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Lipid lowering agent/HMG-CoA reductase inhibitor
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN (ezetimibe and simvastatin) (10/10, 10/20, 10/40, 10/80) tablets USFDA Approved
	Me-too-status	Simbex tablet 10/20 of Searle Pharma (Reg#44049)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was:

		Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation (but reference formulation is uncoated). • The chemistry review Vytorin of USFDA states that in solid state, oxidation of simvastatin can occur, especially at elevated temperature, therefore, butylated hydroxyanisole is added to the drug substance. Butylated hydroxyanisole NF, citric acid monohydrate USP, and propyl gallate NF. • Hence, based on the information extracted from Public assessment report it is concluded that simvastatin losses to thermal degradation in the presence of oxygen, antioxidants shall be added in the formulation. These antioxidants shall also be quantified by suitable test method. The manufacturing of the applied formulation should also be as per innovator that involves the following steps: a) sifting of the main excipients b) preparation of the drug dispersion c) top spray granulation and drying d) spraying of the antioxidants solution on the granules, e) dry screening, f) blending and lubrication g) compression Moreover, the shelf life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. As Zone IV A is more severe condition the shelf life will be more stringent.
	Decision: Approved with innovator's specifications.	
471.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Fabita 80mg Tablet
	Composition	Each film coated Tablet Contains: Febuxostat……..80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10436 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antigout preparation
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	2x10's; ULORIC (40mg, 80mg) film coated tablets USFDA Approved
	Me-too-status	Febuxin 80mg tablet by AGP Ltd (Reg. 081105)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation and did not revise label claim
	Decision: Deferred for revision of formulation as per reference product.	

472.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Jaspir 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10431 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	Me-too-status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5.
	Decision: Deferred for submission of undertaking of Form-5.	
473.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Jaset 8mg Tablet
	Composition	Each film coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…8mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10429 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antiemetics and antinauseants (Serotonin (5HT3) antagonists)
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN (4mg, 8mg) film coated tablets, USFDA Approved
	Me-too-status	Ondan Tablet 8mg by M/s Bio-Mark Pharmaceuticals (Reg#82657)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation and did not revise label claim
	Decision: Deferred for revision of label claim as per reference product alongwith applicable fee.	
474.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Glip 50/1000mg Tablet
	Composition	Each film coated Tablet Contains: Vildagliptin……..50mg Metformin HCl…….1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10433 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019

	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 1,000mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/1000mg Tablets by Novartis Pharma (Reg. No. 66107)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation and did not revise label claim
	Decision: Deferred for revision of label claim as per reference product alongwith applicable fee.	
475.	Name and address of manufacture / Applicant	M/s Jaskon Pharmaceuticals Pvt Ltd 5- Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Glip 50/500mg Tablet
	Composition	Each film coated Tablet Contains: Vildagliptin……50mg Metformin HCl…….500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 10432 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 500mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	Tinmet Tablet 50mg/500mg by M/s Bio-Mark Pharmaceuticals (Reg. No.85718)
	GMP Status	A panel inspection was conducted on 13.03.2018 and conclusion of inspection was: Keeping in view the compliance submitted by the firm and inspection conducted by the panel, the resumption of production to M/s Jakson Pharma Lahore is recommended
	Remark of the Evaluator [XI]	• The firm did not submit undertaking at the end of form 5. • The firm submitted that they have applied for film coated tablet as evident from annexure-F (description of specifications) and master formulation and did not revise label claim
	Decision: Deferred for revision of label claim as per reference product alongwith applicable fee.	
476.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mcolnac 75mg Tablets
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41676 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAIDS
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	VALRON-P 75 Tablets by Venus Pharma (Reg#78831)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of applied formulation in reference regulatory authorities which were adopted by Registration Board in 278th meeting.	
477.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Staprazol Lyophilized Injection 40mg
	Composition	Each Vial Contains: Pantaprazole (as Sodium) ……....40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7533 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Protonix IV 40mg freeze-dried powder USFDA Approved
	Me-too-status	Pancap 40mg injection (lyophilized powder) by M/s Bio-Labs (Reg#75060)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
478.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore.

		Contract Manufactured By: M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Stamop Lyophilized Injection 40mg
	Composition	Each Vial Contains: Omeprazole (as Sodium)……40g
	Dairy No. date of R &I fee	Form-5 Dy.No 7532 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder (lyophilised powder) for Solution for Infusion by MHRA Approved
	Me-too-status	Calsic Injection 40mg IV (lyophilized powder) by M/s Caliph Pharmaceuticals (Reg#82562)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
479.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Staplan Lyophilized Injection 200mg
	Composition	Each Vial Contains: Teicoplanin…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7531 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Glycopeptide antibacterials
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Teicoplanin 200 mg, powder (freeze-dried) for solution for injection/infusion or oral solution. **MHRA** approved
	Me-too-status	Tyclan 200mg lyophilized Injection by M/s MTI Medical (Reg#087922)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018

	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
480.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Staplan Lyophilized Injection 400mg
	Composition	Each Vial Contains: Teicoplanin…..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7530 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Glycopeptide antibacterials
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TARGOCID teicoplanin 400mg lyophilized powder for injection vial with diluent ampoule. TGA approved.
	Me-too-status	Tyclan 400mg lyophilized Injection by M/s MTI Medical (Reg#087923)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
481.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan

	Brand Name + Dosage Form and Strength	Acyclostin Lyophilized Injection 250mg
	Composition	Each Vial Contains: Acyclovir as sodium…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7528 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Antiviral
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aciclovir Powder (freeze-dried) for Infusion 250mg MHRA Approved
	Me-too-status	Friclov Injection 250mg by M/s Friends Pharma (Reg.#099856)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
482.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	E-Stamop Lyophilized Injection 40mg
	Composition	Each Vial Contains: Esomeprazole (as Sodium) ……..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7525 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NEXIUM I.V. (lyophilized cake or powder) for injection USFDA Approved
	Me-too-status	ESUN Injection 40mg by M/s Unison Chemical work (Reg.#081822)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018

	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved with innovator's specifications.	
483.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Acyclostin Lyophilized Injection 500mg
	Composition	Each Vial Contains: Acyclovir as sodium…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7527 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Antiviral
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOVIRAX (250mg, 500mg, 1gm) (lyophilized powder) for Injection USFDA Approved **Discontinued** **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Friclov Injection 500mg by M/s Friends Pharma (Reg.#099857)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved.	
484.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore.

		Contract Manufactured By: M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Stavomycin Lyophilized Injection 1gm
	Composition	Each Vial Contains: Vancomycin (as HCl) …..1gm
	Dairy No. date of R &I fee	Form-5 Dy.No 7526 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 1g Powder (porous cake) for Solution for Infusion MHRA Approved
	Me-too-status	Vinvin 1gm lyophilize Injection by M/s MTI Medical (Reg.#084914)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved.	
485.	Name and address of manufacture / Applicant	M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore. ***Contract Manufactured By:*** M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Stavomycin Lyophilized injection 500mg
	Composition	Each Vial Contains: Vancomycin (as HCl)……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7529 dated 21-02-2019 Rs.50,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Vancomycin 500mg Powder (porous cake) for Solution for Infusion MHRA Approved
	Me-too-status	Vinvin 500mg lyophilize Injection by M/s MTI Medical (Reg.#084915)
	GMP Status	GMP certificate issued to Stallion Pharmaceutical based on inspection dated 22.11.2018 GMP certificate issued to MTI Medical based on inspection dated 17.07.2018

	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Stallion Pharmaceuticals Pvt Ltd, as per approved format • A copy of contract manufacturing agreement between Stallion Pharmaceuticals and MTI Medical (Pvt) Ltd is submitted • The firm submitted list of 04 approved sections of applicant. i.e. M/s Stallion Pharmaceuticals Pvt Ltd • The firm did not have any product registered/approved on contract manufacturing (confirmed from section) • The firm submitted list of 09 applied products for contract manufacturing • Lyophilized Vials Injectable (General) section available with MTI Medical as per licensing division letter No. F. 1-39/2005-Lic (Vol-I)
	Decision: Approved.	
486.	Name and address of manufacture / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Colysin Injection 1 Million IU
	Composition	Each vial contains: Colistimethate Sodium (Lyophilized Powder)……1MIU
	Dairy No. date of R &I fee	Form-5 Dy.No 6953 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antibacterials (polymyxins)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Colistimethate Sodium 1 Million I.U. (lyophilized) Powder for Solution for Injection MHRA Approved
	Me-too-status	Colimate 1000000 IU Injection by MTI Medical (Reg#097779)
	GMP Status	The firm was inspected on 05-08-2019 and conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remark of the Evaluator [XI]	• The firm has claimed for BP specifications but the official monograph is available in USP. • The firm has lyophilized vial (General) section granted via letter No. F. 2-20/85-Lic (Vol.III) (M-227) dated 20th June 2011.
	Decision: Approved with USP specifications.	
487.	Name and address of manufacture / Applicant	M/s Z.Jans Pharmaceuticals Pvt Ltd. 148-A, Hayat Abad Industrial Estate, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Cesef DS 200mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefixime as trihydrate…….200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5671 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019 ***Duplicate dossier***
	Pharmacological Group	Third-generation cephalosporins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	SUPRAX 200mg/5ml Dry Powder Suspension USFDA Approved.
	Me-too-status	Rofixime DS Suspension by SPL Pharmaceuticals (Pvt) Ltd, (Reg#45506)
	GMP Status	The firm was inspected on 03-07-2018 & 02-08-2018 and conclusion of inspection was: The firm has rectified most of the deficiencies observed during the first visit of the panel. Keeping in view the above and positive attitude of the firm towards improvements. The panel unanimously recommend the grant of GMP certificate.
	Remark of the Evaluator [XI]	• The firm has submitted copy of fee challan No. 0796514 deposited on dated 06.02.2019 • The firm revised the 1st page of form 5 as per approved format but the name of the product mentioned was different from the applied "**D/S Cefest DS 200mg/5ml".** • The firm has submitted master formulation for dry suspension and manufacturing method outline.
	Decision: Approved. Fee shall be verified as per procedure adopted in 285th meeting.	
488.	Name and address of manufacture / Applicant	M/s Z.Jans Pharmaceuticals Pvt Ltd. 148-A, Hayat Abad Industrial Estate, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Ibo-Z DS 200mg/5ml Suspension
	Composition	Each 5ml Contains: Ibuprofen……200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5672 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019 ***Duplicate dossier***
	Pharmacological Group	NSAIDs
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ibuprofen 200mg/5ml Oral Suspension (MHRA Approved)
	Me-too-status	Mfin Suspension 200mg/5ml M/s Bio-Mark Pharmaceuticals (Reg#85691)
	GMP Status	The firm was inspected on 03-07-2018 & 02-08-2018 and conclusion of inspection was: The firm has rectified most of the deficiencies observed during the first visit of the panel. Keeping in view the above and positive attitude of the firm towards improvements. The panel unanimously recommend the grant of GMP certificate.
	Remark of the Evaluator [XI]	• The firm has submitted copy of fee challan No. 0796512 deposited on dated 06.02.2019 • The firm revised the 1st page of form 5 as per approved format • The firm has submitted master formulation of the applied product and manufacturing method outline.
	Decision: Approved. Reference shall be sent to budget and accounts for verification of fee challan.	
489.	Name and address of manufacture / Applicant	M/s Z.Jans Pharmaceuticals Pvt Ltd. 148-A, Hayat Abad Industrial Estate, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Terbix DS Tablet 250mg
	Composition	Each tablet contains: Terbinafine (as HCl)…….250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5670 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019 ***Duplicate dossier***

	Pharmacological Group	Antifungals for systemic use
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg tablets MHRA Approved
	Me-too-status	Fibet Tablet 250mg by M/s Bio-Mark Pharmaceuticals (Reg#85717)
	GMP Status	The firm was inspected on 03-07-2018 & 02-08-2018 and conclusion of inspection was: The firm has rectified most of the deficiencies observed during the first visit of the panel. Keeping in view the above and positive attitude of the firm towards improvements. The panel unanimously recommend the grant of GMP certificate.
	Remark of the Evaluator [XI]	• The firm has applied the product as "Terbinafine HCl instead of Terbinafine as HCl" not considering the salt factor. The firm did not revise the label claim as per reference formulation and did not adjust its weight in master formulation neither submitted applicable fee. • The firm has submitted copy of fee challan No. 0796513 deposited on dated 06.02.2019 • The firm revised the 1st page of form 5 as per approved format • The firm has submitted manufacturing method outline.
	Decision: Deferred for revision of label claim as per reference product.	
490.	Name and address of manufacture / Applicant	M/s GT Pharma (Pvt) Ltd. 23km, Raiwind Road, Lahore ***Contract Manufactured By:*** M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Nestor Syrup 4mg/5ml
	Composition	Each 5ml of syrup contains: Ondansetron HCl……4mg
	Dairy No. date of R &I fee	Dy.No 8289 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Antiemetics and antinauseants (Serotonin (5HT3) antagonists)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN 4mg/5ml oral solution USFDA Approved
	Me-too-status	Ondan syrup 4mg/5ml by M/s Bio-mark Pharmaceuticals (Reg#082628)
	GMP Status	M/s GT Pharma was inspected on 08-08-2017 and conclusion of inspection was: Keeping in view the observations made on the day of inspection and after going through the documentation and overall operations, the panel of inspectors was of the opinion that the firm M/s GT Pharma Lahore had maintained conformance to GMP compliance in the manufacturing and quality control operations. GMP Certificate issued to M/s Medisave Pharma on 15-03-2018 based on inspection conducted on 11-12-2017 & 10-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted the applicant i.e. M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore.

		• The firm has revised the label claim along with submission of Rs. 5000/- on deposit slip No.1957092 dated 03-08-2020. The revised label claim is as under: Each 5ml of syrup contains: Ondansetron HCl dihydrate eq. to Ondansetron……4mg • The firm submitted undertaking at the end of form 5 is but signed by the CEO of Medisave pharma and not by the technical persons. • The firm submitted a copy of contract manufacturing agreement between M/s GT Pharma and M/s Medisave Pharmaceuticals • The firm submitted a list of 04 approved sections of applicant • The firm informed that they have no products already registered/approved on contract manufacturing in the name of applicant • The firm submitted a list of 20 products applied on contract manufacturing.
	Decision: Approved.	
491.	Name and address of manufacture / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Road, Layyah, Punjab
	Brand Name + Dosage Form and Strength	Reglin 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin……75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8091 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	2x7's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 75mg Capsules by M/s Getz Pharma (Reg#47365)
	GMP Status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remark of the Evaluator [XI]	• The firm submitted original undertaking at the end of form 5 duly signed by the technical persons • The firm submitted manufacturing outline for capsule.
	Decision: Approved.	
492.	Name and address of manufacture / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name + Dosage Form and Strength	Reglin 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin……..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8090 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	2x7's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 50mg Capsules by M/s Getz Pharma (Reg#48725)

	GMP Status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remark of the Evaluator [XI]	• The firm submitted original undertaking at the end of form 5 duly signed by the technical persons • The firm submitted manufacturing outline for capsule.
	Decision: Approved.	
493.	Name and address of manufacture / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name + Dosage Form and Strength	Reglin 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin……..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8092 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form-5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	2x7's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsules, USFDA Approved
	Me-too-status	Gabica 100mg Capsules by M/s Getz Pharma (Reg#47366)
	GMP Status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remark of the Evaluator [XI]	• The firm submitted undertaking at the end of form 5 duly signed by the technical persons • The firm submitted manufacturing outline for capsule.
	Decision: Approved.	
494.	Name and address of manufacture / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name + Dosage Form and Strength	Dlans 60mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) ……..…60mg (Source of pellets Vision Pharma)
	Dairy No. date of R &I fee	Form-5 Dy.No 8089 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	1x10's, 3x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	Me-too-status	Razodex 60mg capsule by M/s Getz Pharma (Reg#086977)
	GMP Status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remark of the Evaluator [XI]	• The firm submitted stability studies data of three batches but not as per Requirements of Registration Board decision of 293rd meeting. • The firm submitted original undertaking at the end of form 5 duly signed by the technical persons • The firm submitted valid GMP certificate of Vision pharmaceticals (supplier of pellets)

	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
495.	Name and address of manufacture / Applicant	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab
	Brand Name + Dosage Form and Strength	Dlans 30mg Capsules
	Composition	Each Capsule Contains: Dexlansoprazole (DDR Pellets 22.5% equivalent to Dexlansoprazole) …..…30mg (Source of pellets Vision Pharma)
	Dairy No. date of R &I fee	Form-5 Dy.No 8088 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	1x10's, 3x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	Me-too-status	Razodex 30mg capsule by M/s Getz Pharma (Reg#086976)
	GMP Status	Last GMP inspection was conducted on 03-05-2019 in which the panel recommended the renewal of DML and grant of additional sections to M/s Pharma Lord (Pvt) Ltd.
	Remark of the Evaluator XI	• The firm submitted stability studies data of three batches but not as per Requirements of Registration Board decision of 293rd meeting. • The firm submitted original undertaking at the end of form 5 duly signed by the technical persons • The firm submitted valid GMP certificate of Vision pharmaceuticals (supplier of pellets).
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
496.	Name and address of manufacture / Applicant	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Hyonim 10mg Tablet
	Composition	Each Tablet Contains: Hyoscine butylbromide ……..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8521 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antispasmodic
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	BUSCOPAN hyoscine butylbromide 10mg sugar tablet TGA Approved
	Me-too-status	Caragen Tablets 10 mg tablet by M/s Caraway Pharmaceuticals, (Reg#69928)
	GMP Status	**Resumption of Production Notice was issued on 31-07-2019**
	Remark of the Evaluator XI	• The firm revised the label claim from uncoated to sugar coated tablets without submission of applicable fee. The revised label claim is as under: Each sugar-coated tablet Contains: Hyoscine butylbromide …….. 10mg Furthermore, the submitted revised master formulation
	Decision: Deferred for submission of applicable fee for revision of formulation.	

497.	Name and address of manufacture / Applicant	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Xynim 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Levocetirizine dihydrochloride ……..…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8520 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Piperazine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL 5mg film coated tablet USFDA Approved
	Me-too-status	Norzin 5mg film coated tablets by M/s Nortech Pharmaceuticals (Reg# 77965)
	GMP Status	**Resumption of Production Notice was issued on 31-07-2019**
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
498.	Name and address of manufacture / Applicant	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Des-Zine Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Desloratadine……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8519 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihistamine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex 5mg film coated tablet USFDA Approved.
	Me-too-status	Desatil Tablets 5mg by Aries Pharmaceuticals (Reg#84270)
	GMP Status	**Resumption of Production Notice was issued on 31-07-2019**
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
499.	Name and address of manufacture / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name + Dosage Form and Strength	Agomel Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Agomelatine…….25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8801 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antidepressant
	Type of form	Form 5
	Finished product specifications	In-house specifications
	Pack size and Demand Price	7's, 10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Valdoxan (Agomelatine) 25mg Film-Coated Tablets TGA Approved
	Me-too-status	Agoviz 25mg tablet of M/s PharmEvo (Reg#086887)
	GMP Status	The firm was inspected on 29-08-2019 and conclusion of inspection was:

		Based on areas visited, people met, commitment of the firm for further improvement, it is concluded that the firm is operating at a Good level of GMP compliance.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
500.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Aprowim 150mg Tablet Apromit 150mg Tablet
	Composition	Each film coated tablet contains: Irbesartan ……..…. 150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12135 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 1x28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ABISART 150 irbesartan 150mg film coated tablet TGA approved.
	Me-too-status	Irbisaff Tablet 150mg by M/s Saffron Pharmaceuticals (Reg#77189)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for consideration on its turn.	
501.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Aprowim 300mg Tablet Apromit 300mg Tablet
	Composition	Each film coated tablet contains: Irbesartan …. ……..300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12134 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 1x28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ABISART 300 irbesartan 300mg film coated tablet TGA approved.
	Me-too-status	Irbisaff Tablet 300mg by M/s Saffron Pharmaceuticals (Reg#77188)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for consideration on its turn.	
502.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Oseltawir 75mg Capsule Infu-Wim 75mg Capsule
	Composition	Each Capsule contains: Oseltamivir phosphate equivalent to oseltamivir …. 75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12120 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Neuraminidase Inhibitor
	Type of form	Form-5
	Finished product specifications	USP

	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TAMIFLU (30mg, 45mg, 75mg) capsules (USFDA approved).
	Me-too-status	Ostavir-Flu 75mg Capsule by Zafa Pharmaceutical (Reg#42333)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for consideration on its turn.	
503.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Lorwim 25mg Tablet Lormit 25mg Tablet
	Composition	Each film coated tablet contains: Losartan Potassium …… 25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12119 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar 25mg film-coated tablets. MHRA approved
	Me-too-status	Lotass 25mg Tablet by M/s Getz Pharma (Reg# 66802)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for consideration on its turn.	
504.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Lorwim 50mg Tablet Lormit 50mg Tablet
	Composition	Each film coated Tablet contains: Losartan Potassium …. 50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12121 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar 50 mg film-coated tablets. MHRA approved
	Me-too-status	Lotass 50mg Tablet by M/s Getz Pharma (Reg# 66803)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	•
	Decision: Deferred for consideration on its turn.	
505.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	NISIM 100mg Tablet
	Composition	Each Tablet contains: Nimesulide …….. 100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12133 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	NSAIDS
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ALGIMESIL 100 mg tablets AIFA Italy Approved
	Me-too-status	Nimcid Tablets by Unexolabs (Reg#46336)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	• The firm revised master formulation and manufacturing outline and removed coating composition and coating procedure.
	Decision: Deferred for consideration on its turn.	
506.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Passit 10mEq tablet Citro-P 10mEq tablet
	Composition	Each Extended release tablet contains: Potassium Citrate …. 10mEq (1080mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 12122 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Urinary Alkalinizing agent
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Urocit-K Extended-release tablets USFDA Approved
	Me-too-status	Exocite XR 10mEq tablets by M/s Vision Pharmaceuticals (Reg#080827)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	• The firm has claimed manufacturer's specifications but the official monograph is available in USP. • The firm submitted undertaking at the end of form 5 duly signed by the technical persons. • The firm submitted complete master formulation and manufacturing method for the applied product.
	Decision: Deferred for consideration on its turn.	
507.	Name and address of manufacture / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form and Strength	Thiowim Injection 4mg/2ml
	Composition	Each 2ml ampoule contains: Thiocolchicoside …… 4mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12126 dated 06-03-2019 Rs.20,000 Dated 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of form	Form-5
	Finished product specifications	
	Pack size and Demand Price	6ampx2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	THIOCOLCHICOSIDE PHARMY II 4 mg/2 ml, solution for injection ampule. ANSM approved
	Me-too-status	Thiocol 4mg / 2ml Injection by M/s Ray Pharma (Reg#66712)
	GMP Status	GMP Certificate issued on 10-12-2018.
	Remark of the Evaluator [XI]	• Firm informed the use of type I glass container as primary packaging material of applied formulation • The firm has applied for USP specifications and the product is not present in available pharmacopoeias.

	Decision: Deferred for consideration on its turn.	
508.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Amval Tablets 5/80mg
	Composition	Each Film Coated Tablet Contains: Amlodipine besylate……5mg Valsartan……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9949 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm corrected the salt form of amlodipine in the label claim along with submission of Rs. 5000/- on deposit slip No. 2032335 date 05-08-2020. The revised label claim is as under; Each Film Coated Tablet Contains: Amlodipine as besylate……5mg Valsartan……80mg • They also revised coating composition from enteric coating to film coating.
	Decision: Approved.	
509.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	CE-Med 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine Dihydrochloride…….10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9950 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-Histamine
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	2x15's;As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine Dihydrochloride 10mg film-coated tablets (MHRA approved)
	Me-too-status	Atcet 10mg Tablet by M/s Atco LabKart. (Reg. # 83214)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation and changed coating composition as per reference formulation (removed Eudragit E100 which is used as coating material for pH controlled drug release from coating composition)
	Decision: Approved.	
510.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan

	Brand Name + Dosage Form and Strength	Hi-Claro 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9844 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 500mg Film-coated Tablets. MHRA approved
	Me-too-status	Clarital 500mg Tablet. By M/s Arsons Pharmaceuticals (Reg. No. 85500)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation and changed coating composition as per reference formulation (removed Eudragit E100 which is used as coating material for pH controlled drug release from coating composition)
	Decision: Approved.	
511.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Hi-Claro 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin……..250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9940 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 250mg Film-coated Tablets. MHRA approved
	Me-too-status	Clarital 250mg Tablet. By Arsons Pharmaceuticals Industries (Pvt) Ltd., (Reg. No. 85501)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation and changed coating composition as per reference formulation (removed Eudragit E100 which is used as coating material for pH controlled drug release from coating composition) • Undertaking at the end of form 5 not signed by the technical persons
	Decision: Approved.	
512.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Medonac 75mg Tablet
	Composition	Each enteric coated tablet contains: Diclofenac sodium……..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9946 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	NSAIDS

	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	VOLTAREN (25mg, 50mg, 75mg) Delayed Release/ enteric-coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Torelief 75mg Tablet by M/s Maple Pharmaceuticals (Reg.# 058203)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Revise the 1st page of form 5 as per approved format • Undertaking at the end of form 5 is not signed by the technical persons. • All the details of form 5 submitted are of the wimits pharmaceuticals, clarify?
	Decision: Deferred for clarification regarding submission of details of M/s Wimits pharmaceuticals while applied product is for Hi-Med Pharmaceuticals	
513.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Festat 80mg Tablet
	Composition	Each Tablet Contains: Febuxostat……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9948 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antigout preparation
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC (40mg, 80mg) film coated tablets USFDA Approved
	Me-too-status	Febuxin 80mg tablet by AGP Ltd (Reg. 081105)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm submitted revised Form 5 as per approved format duly signed by the signatory. • The firm revised the label claim from uncoated to film coated tablet along with submission of Rs. 5000/- on deposite slip No. 2037410 dated 05-08-2020. The revised label claim is as under; Each film coated Tablet Contains: Febuxostat……80mg
	Decision: Approved with innovator's specifications.	
514.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Fexomed 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl……..…120mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9943 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antihistamines
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	Telfast 120mg film-coated tablets, MHRA Approved.
	Me-too-status	Nifty 120mg Tablet by M/s Maxitech Pharma, (Reg#83707)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• The firm revised the label claim and corrected the salt form of fexofenadine along with submission of Rs. 5000/- on deposit slip No. 2022358 dated 05-08-2020. The revise label claim is as under; Each Film Coated Tablet Contains: Fexofenadine as HCl……..…120mg
	Decision: Approved.	
515.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Gemocin 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin mesylate eq to Gemifloxacin…320mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9935 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of form	Form-5
	Finished product specifications	In-house
	Pack size and Demand Price	7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Factive 320mg film-coated tablet (**USFDA** Approved)
	Me-too-status	Renova 320mg Tablet by M/s Sami Pharmaceuticals (Reg#70788)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Undertaking at the end of form 5 is not signed by the technical persons.
	Decision: Approved with innovator's specifications.	
516.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Med-Q Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate eq to Quetiapine ……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9937 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 200mg) MHRA Approved.
	Me-too-status	Qupixan Tablet 25mg by Regal Pharmaceuticals (Reg#81960)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
517.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan

	Brand Name + Dosage Form and Strength	Med-Q Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate eq to Quetiapine …….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9936 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antipsychotics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 200mg) MHRA Approved.
	Me-too-status	Qupixan Tablet 100mg by Regal Pharmaceuticals (Reg#81961)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
518.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Risdon tablet 1mg
	Composition	Each Film Coated Tablet Contains: Risperidone……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9941 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antipsychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x6's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperidone 1mg Film-Coated Tablets MHRA approved
	Me-too-status	Neo-Risp Tablet 1mg by Wilshire laboratories, (Reg#85184)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	
	Decision: Approved.	
519.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Medigex 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sertraline as HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9947 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	LUSTRAL 50mg film coated tablets MHRA Approved
	Me-too-status	Seralin 50mg Tablet by M/s Bosch Pharmaceuticals (Reg#83323)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	•

	Decision: Approved.	
520.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Citamed 50mg/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin phosphate monohydrate eq to sitaglitpin..50mg Metformin HCl……..…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9952 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) USFDA Approved.
	Me-too-status	Silmax-M 50mg/500mg Tablet by M/s High-Q Pharmaceuticals (Reg#76399)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Undertaking at the end of form 5 is not signed by the technical persons.
	Decision: Approved with innovator's specifications.	
521.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Tizamed 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine (as HCl)……4mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9942 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZANAFLEX 4mg uncoated tablets USFDA approved
	Me-too-status	Lozeden 4mg Tablet by M/s Lowitt Pharmaceuticals (Reg#84231)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Undertaking at the end of form 5 is not signed by the technical persons. • The firm submitted revised manufacturing outline for uncoated tablets.
	Decision: Approved.	
522.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Medviline 50mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……...1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9938 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 1,000mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/1000mg Tablets by Novartis Pharma (Reg. No. 66107)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Undertaking at the end of form 5 is not signed by the technical persons.
	Decision: Approved with innovator's specifications.	
523.	Name and address of manufacture / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Medviline 50mg/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl…….850mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9953 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 850mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/850mg TABLETS by Novartis Pharma (Reg. No. 66106)
	GMP Status	The firm M/s Himed Pharma was inspected on 7.04.2018, wherein grant of DML was recommended for 4 sections.
	Remark of the Evaluator [XI]	• Undertaking at the end of form 5 is not signed by the technical persons.
	Decision: Approved with innovator's specifications.	
524.	Name and address of manufacture / Applicant	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Rumadol 50mg Capsule
	Composition	Each Capsule Contains: Tramadol HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7405 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Opioids Analgesic
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol Hydrochloride 50mg Capsules. MHRA approved
	Me-too-status	Antram plus 50mg Capsules by Dr Raza Pharma (Reg# 84244)
	GMP Status	Decision of the 270th Meeting of CLB: After thorough discussion/deliberations and recommendation of the panel of experts in its report dated 14-05-2019, the Central Licensing Board decided to: I- Resume production activities in Human Liquid Injection Section (Genera-Ampoule) Only.

		II- However production will remain suspended in Human Injectable Section (Psychotropic), till the improvements made by the firm, verification by the panel of experts.
	Remark of the Evaluator [XI]	• The firm submitted complete manufacturing outline mentioning blistering and packing processes. • The firm submitted undertaking available at the end of form 5
	Decision: Approved.	
525.	Name and address of manufacture / Applicant	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Rumadol 50mg Injection
	Composition	Each 1ml ampoule contains: Tramadol HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7404 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Opioids Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMAL tramadol hydrochloride 50mg/1mL injection ampoule TGA Approved
	Me-too-status	Palmadol Injection 50mg by Palpex Pharmaceuticals (Reg#82969)
	GMP Status	Decision of the 270th Meeting of CLB: After thorough discussion/deliberations and recommendation of the panel of experts in its report dated 14-05-2019, the Central Licensing Board decided to: I- Resume production activities in Human Liquid Injection Section (Genera-Ampoule) Only. II- However production will remain suspended in Human Injectable Section (Psychotropic), till the improvements made by the firm, verification by the panel of experts.
	Remark of the Evaluator [XI]	• The firm informed that they will perform asceptic filling and did not mentioned terminal sterilization in manufacturing outline. • The firm informed the use of type I glass container as primary packaging material of applied formulation • The firm submitted undertaking available at the end of form 5
	Decision: Deferred for clarification / justification for not performing terminal sterilization step for applied formulation.	
526.	Name and address of manufacture / Applicant	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Rumadol 100mg Injection
	Composition	Each 2ml Ampoule Contains: Tramadol HCl…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7403 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Opioids Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMAL tramadol hydrochloride 100mg/2mL injection ampoule TGA Approved

	Me-too-status	Amadrol Injection 100mg/ 2 ml by M/s Amarant Pharmacetuicals (Reg#83042)
	GMP Status	Decision of the 270th Meeting of CLB: After thorough discussion/deliberations and recommendation of the panel of experts in its report dated 14-05-2019, the Central Licensing Board decided to: I- Resume production activities in Human Liquid Injection Section (Genera-Ampoule) Only. II- However production will remain suspended in Human Injectable Section (Psychotropic), till the improvements made by the firm, verification by the panel of experts.
	Remark of the Evaluator [XI]	• The firm informed that they will perform asceptic filling and did not mentioned terminal sterilization in manufacturing outline. • The firm informed the use of type I glass container as primary packaging material of applied formulation
	Decision: Deferred for clarification / justification for not performing terminal sterilization step for applied formulation.	
527.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Libri 5/2.5mg Capsules
	Composition	Each Capsule Contains: Chlordiazepoxide Hydrochloride…5mg Clidinium Bromide…2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39663 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Anxiolytics and anticholinergic/spasmolytic combinations
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Librax Capsules (USFDA Approved)
	Me-too-status	Could not be verified
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • Evidence of psychotropic section. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be verified.
	Decision: Deferred for following: **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **Confirmation of required manufacturing facility for applied formulation.**	
528.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Cilaaz 100mg Tablet
	Composition	Each film coated Tablet Contains: Cilostazol……..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39896 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Platelet aggregation inhibitor
	Type of form	Form 5

	Finished product specifications	USP
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PLETAL cilostazol 100 mg tablet of Otsuka Australia Pharmaceutical Pvt Ltd (TGA Approved)
	Me-too-status	Pletaal Tablets 100mg by M/s Otsuka Pakistan Ltd, (Reg#029295)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation does not contain coating. Revise the label claim and master formulation along with submission of applicable fee.
	Decision: Deferred for revision of label claim and master formulation as per referemce product alongwith requisite fee.	
529.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ozap 100mg Tablet
	Composition	Each film coated Tablet Contains: Clozapine…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39673 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clozaril tablets (USFDA Approved)
	Me-too-status	Zydex-100 Tablets by Genome Pharmaceuticals (Pvt,) Ltd (Reg#53559)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation does not contain coating. Revise the label claim and master formulation along with submission of applicable fee.
	Decision: Deferred for revision of label claim and master formulation as per referemce product alongwith requisite fee.	
530.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ozap 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Clozapine…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39672 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clozaril tablets (USFDA Approved)

	Me-too-status	Zydex-25 Tablets by Genome Pharmaceuticals (Pvt,) Ltd (Reg#53558)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation does not contain coating. Revise the label claim and master formulation along with submission of applicable fee.
	Decision: Deferred for revision of label claim and master formulation as per reference product alongwith requisite fee.	
531.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Cindela 450mg Tablet
	Composition	Each film coated Tablet Contains: Delafloxacin (as meglumine)…450mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39895 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Fluoroquinolones
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	BAXDELA Tablets 450 mg (USFDA Approved)
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation does not contain coating. Revise the label claim and master formulation along with submission of applicable fee. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: **Revision of label claim and master formulation alongwith applicable fee.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
532.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Emplina 10/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin…10mg Linagliptin……..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39668 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GLYXAMBI (USFDA Approved)

	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for uncoated tablets while the reference formulation is film coated. Revise the label claim and master formulation along with submission of applicable fee. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: **Submission of application on Form-5D alongwith applicable fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
533.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Emplina 25/5mg Tablets
	Composition	Each Tablet Contains: Empagliflozin…25mg Linagliptin…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39669 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GLYXAMBI (USFDA Approved)
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for uncoated tablets while the reference formulation is film coated. Revise the label claim and master formulation along with submission of applicable fee. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: **Submission of application on Form-5D alongwith applicable fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
534.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ertusit 15/100mg Tablet
	Composition	Each Film coated Tablet Contains: Ertugliflozin (L-pyroglutamic acid)…15mg Sitagliptin (Phosphate Monohydrate)…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39664 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs

	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	STEGLUJAN (USFDA Approved)
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The applied formulation is also not as per reference formulation, revise the formulation along with submission of fee.
	Decision: Deferred for following: **Submission of application on Form-5D alongwith applicable fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
535.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Metiva 5/50mg Tablet
	Composition	Each Tablet Contains: Ivabradine (as HCL)…5mg Metoprolol Tartrate…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39670 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Beta blocking agents, other combinations
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IMPLICOR 5 mg / 50 mg film-coated tablet (ANSM France Approved)
	Me-too-status	Implicor 5/50 mg of Serveir and Research Pharmacuticals Pakistan (Reg#099006)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for uncoated tablets while the reference formulation is film coated. Revise the label claim and master formulation along with submission of applicable fee.
	Decision: Deferred for following: **Revision of label claim and master formulation alongwith applicable fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
536.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Metiva 7.5/50mg Tablet
	Composition	Each Tablet Contains: Ivabradine (as HCl)…7.5mg Metoprolol Tartrate…50mg

	Dairy No. date of R &I fee	Form-5 Dy.No 39671 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Beta blocking agents, other combinations
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IMPLICOR 7.5 mg / 50 mg film-coated tablet (ANSM France Approved)
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 10-02-2020 and reminder on 21-05-2020 but no reply received yet • The submitted formulation does not contain coating while the reference formulation is film coated. Revise the label claim and master formulation along with submission of applicable fee. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: **Revision of label claim and master formulation alongwith applicable fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
537.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Maciten 10mg Tablet
	Composition	Each film coated Tablet Contains: Macitentan…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39662 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	OPSUMIT 10mg tablet USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline doesd not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines provided in 293rd meeting of Registration Board.	
538.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Oxego 25mg Tablets
	Composition	Each Film Coated Tablet Contains: Naloxegol (as Oxalate)…25mg

	Dairy No. date of R &I fee	Form-5 Dy.No 39667 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Peripheral opioid receptor antagonists
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 15's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MOVANTIK 25mg tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline doesd not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines provided in 293rd meeting of Registration Board.	
539.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Perfen Tablet 801mg
	Composition	Each Film Coated Tablet Contains: Pirfenidone…801mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39666 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Immunosuppressants
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ESBRIET film-coated tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline doesd not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for following: **Submission of application on Form-5D alongwith differential fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
540.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Riocit 0.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Riociguat…0.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39676 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018

	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ADEMPAS 0.5mg tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline doesd not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines provided in 293rd meeting of Registration Board.	
541.	Name and address of manufacture / Applicant	M/s Navegal Laboratories., 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Riocit 1.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Riociguat…1.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39678 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ADEMPAS 1.5mg tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines provided in 293rd meeting of Registration Board.	
542.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Riocit 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Riociguat…1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39677 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications

	Pack size and Demand Price	10's; 14's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ADEMPAS 1mg tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines provided in 293rd meeting of Registration Board.	
543.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Zonisa 100mg Capsule
	Composition	Each Capsule Contains: Zonisamide…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39675 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZONEGRAN 100mg capsules USFDA Approved
	Me-too-status	Seizof 100mg Capsule of OBS Pakistan Reg#73644)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	•
	Decision: Deferred for GMP inspection report within the period of 3 years.	
544.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Zonisa 50mg Capsule
	Composition	Each Capsule Contains: Zonisamide…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39674 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zonisamide Warren 50mg capsule MHRA Approved
	Me-too-status	Seizof 50mg Capsule of OBS Pakistan Reg#73643)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	•
	Decision: Deferred for GMP inspection report during last 3 years.	
545.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar

	Brand Name + Dosage Form and Strength	Onidi ER 0.1mg Tablet
	Composition	Each extended release tablet contains: Clonidine HCl…0.1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39890 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antiadrenergic Agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 15's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	KAPVAY 0.1mg extended-release tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 11-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • You have applied film coated tablets while the reference formulation is uncoated extended release, revise the master formulation alongwith submission of applicable fee.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
546.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Onidi ER 0.2mg Tablet
	Composition	Each extended release tablet contains: Clonidine HCl…0.2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39891 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antiadrenergic Agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 15's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	KAPVAY 0.2mg extended-release tablets USFDA Approved **Discontinued "**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • You have applied film coated tablets while the reference formulation is uncoated extended release, revise the master formulation alongwith submission of applicable fee.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

547.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Difural 240mg Capsules
	Composition	Each gastro-resistant hard capsule contains: Dimethyl Fumarate…240mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39893 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Immunosuppressants
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TECFIDERA delayed-release capsules, USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • You have applied for delayed release pellets filled into hard gelatin capsules, while the reference formulations contain enteric coated microtablets filled into hard gelatin capsule. Justify? Or revise the label claim and master formulation along with submission of applicable fee. • Provide evidence of machinery used for manufacturing of microtablets.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
548.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Vermeil DR 10/10mg Tablet
	Composition	Each film coated delayed Release Tablet contains: Doxylamine Succinate…10mg Pyridoxine HCl…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39886 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antihistamines
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too-status	Omit 10/10 mg Tablet by Scilife Pharma (Reg#82087)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • The reference formulation is film coated delayed release tablets while the applied product manufacturing outline does not contain any such steps. Please revise the manufacturing outline as per reference formulation
	Decision: Deferred for revision of manufacturing outline as per reference formulation.	

549.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Ezecol 10mg Tablets
	Composition	Each film coated Tablet Contains: Ezetimibe…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39892 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Lipid Lowering Agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zetia Tablet MHRA Approved
	Me-too-status	Preveze Tablets 10 mg by Highnoon Laboratories, (Reg#42566)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablets while the reference formulation is uncoated tablets. Revise the label and master formulation alongwith submission of applicable fee.
	Decision: Deferred for revision of label claim and master formulation alongwith applicable fee.	
550.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Laurel 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Lurasidone HCl…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39899 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti-psychotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 15's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too-status	Luda 40mg tablets of Genome pharmaceuticals (Reg#095154)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
551.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Laurel 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Lurasidone HCl…80mg

	Dairy No. date of R &I fee	Form-5 Dy.No 39900 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti-psychotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 15's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too-status	Rasidon 80mg tablets of Hilton pharma (Reg#089371)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
552.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Begron ER 25mg Tablets
	Composition	Each extended release tablet contains: Mirabegron……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39894 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Urinary Anti- spasmodics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 15's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ extended-release tablets USFDA Approved
	Me-too-status	Mirabet 25mg tablets of CCL Pharma (Reg#090378)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
553.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Begron ER 50mg Tablets
	Composition	Each extended release tablet contains: Mirabegron……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39897 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Urinary Anti- spasmodics
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 15's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ extended-release tablets USFDA Approved
	Me-too-status	Mirabet 50mg tablets of CCL Pharma (Reg#090503)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 12-02-2020 and reminder on 21-05-2020 but no reply received yet • The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
554.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Rofumil 500µg Tablets
	Composition	Each Film Coated Tablet Contains: Roflumilast……...500µg
	Dairy No. date of R &I fee	Form-5 Dy.No 39898 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Daxas 500µg film-coated tablets EMA Approved
	Me-too-status	Omlast 500µg tablets by Genix Pharma (Reg#100192)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Submission of stability studies data as per Requirements of Registration Board decision of 251st meeting. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
555.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Fampira 10mg Tablets
	Composition	Each Tablet Contains: Amifampridine……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41417 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other nervous system drugs
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO

	Approval status of product in Reference Regulatory Authorities	RUZURGI tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The applied formulation is uncoated tablets while you have mentioned film coating in master formulation. Revise the master formulation accordingly
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
556.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Aprem 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Apremilast……..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41412 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Selective immunosuppressants
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	OTEZLA tablet USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly • Signature of the technical staff is missing on the undertaking.
	Decision: Deferred for following: **Submission of application on Form-5D alongwith differential fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
557.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Aprem 30mg Tablets
	Composition	Each Film Coated Tablet Contains: Apremilast…….30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41413 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Selective immunosuppressants

	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	OTEZLA tablet USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for following: **Submission of application on Form-5D alongwith differential fee.** **Submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.**	
558.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Colozid 1.1g Tablet
	Composition	Each Film Coated Tablet Contains: Balsalazide Disodium…1100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41415 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for followings: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**	
559.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar

	Brand Name + Dosage Form and Strength	Bivoson 5/80mg Tablets
	Composition	Each Film Coated Tablet Contains: Nebivolol (as HCL)……5mg Valsartan……...80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41414 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	B-adrenergic Receptor blocking Agent, Angiotensin II Receptor Blocker
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for followings: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**	
560.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Prandlin 1mg Tablet
	Composition	Each Tablet Contains: Repaglinide……..1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41421 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other blood glucose lowering drugs, excl. insulins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Repag 1mg Tablet by Getz Pharma (Pvt)Ltd, (Reg#57891)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • You have applied for film coated tablet while the reference formulation is uncoated. Revise the label claim and master formulation along with submission of applicable fee.

	Decision: Deferred for revision of label claim and master formulation as per reference formulation alongwith applicable fee and GMP inspection during 3 years.	
561.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Pental ER 200mg Tablet
	Composition	Each extended release film coated tablet contains: Tapentadol (as HCl)……200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41420 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Opioid Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA ER extended-release tablets USFDA Approved
	Me-too-status	Tapento XR tablets by Sami Pharmaceuticals (Reg#93062)
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Submission of stability studies data as per Requirements of Registration Board decision of 251st meeting. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
562.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Pental 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol (as HCl)…….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41419 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Opioid Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator [XI]	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submission of stability studies data as per Requirements of Registration Board decision of 251st meeting. • You have applied for film coated tablets while master formulation and manufacturing outline does not contain film coating ingredients and coating process. Submit master formulation and complete manufacturing outline

	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
563.	Name and address of manufacture / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name + Dosage Form and Strength	Pental 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol (as HCl)…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41418 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Opioid Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	NUCYNTA tablets USFDA Approved
	Me-too-status	
	GMP Status	The firm was inspected on 11-03-2017 was found to be operated at satisfactory level of **GMP compliance.**
	Remark of the Evaluator XI	• Letter of deficiencies sent on 21-02-2020 and reminder on 21-05-2020 but no reply received yet • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submission of stability studies data as per Requirements of Registration Board decision of 251st meeting. • The applied formulation is film coated tablets while the submitted manufacturing outline does not contain coating process. Submit complete manufacturing outline accordingly
	Decision: Deferred for submission of stability study data as per guidelines provided in 293rd meeting of Registration Board.	
564.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form and Strength	Stazic Tablet 50mg
	Composition	Each Tablet Contains: Cilostazol……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9519 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antithrombotic Agents
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	2x14's, 4x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PLETAL cilostazol 50 mg tablet (TGA Approved)
	Me-too-status	Plator Tablet 50mg by M/s Don Valley Pharmaceuticals (Reg#69367)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator XI	•

	Decision: Approved.	
565.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form and Strength	Pride 50mg Tablet
	Composition	Each film coated tablet contains: Itopride HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9522 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Propulsives
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10, 20, 40, 90, 100; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 50mg tablet (PMDA) Japan Approved
	Me-too-status	Xepride tablet 50mg of M/s Usawa Pharmaceuticals (Reg. # 076818)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
566.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore.
	Brand Name + Dosage Form and Strength	Nusyn 30mg Tablet
	Composition	Each film coated tablet contains: Nimodipine……30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9524 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects
	Type of form	Form-5
	Finished product specifications	BP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nimotop 30mg film coated Tablets Of MHRA approved
	Me-too-status	Nimovas 30mg Tablet by M/s Spencer Pharma (Reg#67697)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
567.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore

	Brand Name + Dosage Form and Strength	Pinrole 2mg Tablet
	Composition	Each film coated tablet contains: Ropinirole as HCl……..…2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9526 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	3x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP (0.25, 0.5, 1, 2, 3, 4, or 5mg) film-coated tablets, USFDA approved
	Me-too-status	XMG 2mg Tablet by M/s Atco Labs (Reg#50524)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator [XI]	• The applicant have claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved.	
568.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form and Strength	Pinrole 1mg Tablet
	Composition	Each film coated tablet contains: Ropinirole as HCl….……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9525 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	3x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP (0.25, 0.5, 1, 2, 3, 4, or 5mg) film-coated tablets, USFDA approved
	Me-too-status	XMG 1mg Tablet by M/s Atco Labs (Reg#50523)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator [XI]	• The applicant have claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved.	
569.	Name and address of manufacture / Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form and Strength	Vorzol Tablet 50mg

	Composition	Each film coated tablet contains: Voriconazole……..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9518 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti- fungal
	Type of form	Form-5
	Finished product specifications	Manufacturers
	Pack size and Demand Price	28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, 500; As per SRO
	Approval status of product in Reference Regulatory Authorities	VFEND (50 mg, 200 mg) film-coated tablets, USFDA Approved
	Me-too-status	Voric 50mg Tablet by M/s Genix Pharma (Reg. #83916)
	GMP Status	The firm was inspected on 21,23-08-2017 by a panel of inspectors and conclusion of inspections was: Panel inspected the unit and evaluated documentation regarding production, quality control and quality assurance. Panel discussed various technical aspects with the technical staff at length. Panel decided to recommend the renewal of DML of M/s Neutro Pharma for the approved sections by the Central Licensing Board.
	Remark of the Evaluator [XI]	• The applicant have claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved with innovator's specifications.	
570.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi
	Brand Name + Dosage Form and Strength	Pseudoephedrine 30mg Tablet
	Composition	Each Tablet Contains: Pseudoephedrine……30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9467 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Sympathomimetics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1000's jar; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Pseudoephedrine 30mg Tablet by M/s Safe Pharmaceuticals (Reg.#66739)
	GMP Status	Last GMP inspection conducted on 18-07-2018 and conclusion of inspection was: Based on the above facts the current compliance level is rated as good
	Remark of the Evaluator [XI]	• On 1st page of form 5 and cover letter you have mentioned both pseudoephedrine 30mg tablet (ephedrine 30mg tablet), while in label claim you have mentioned pseudoephedrine 30mg tablet. Clarify? • Fee is deposited on two deposit slips having No. 0829570 dated 01-03-2019 of Rs. 15000/- and 709580 dated 01-03-2019 of Rs. 5000/- and pseudoephedrine 30mg tablet is mentioned on both the slips while on verification of fee challan from budget and accounts ephedrine 30mg tablet is mentioned. • Salt form of API (HCl) • Undertaking at the end of form 5 is missing

		• Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting along with weblink • Provide evidence of manufacturing facility/section approval for the applied formulation
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
571.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi
	Brand Name + Dosage Form and Strength	T-One 2mg Tablet
	Composition	Each Tablet Contains: Lorazepam……2mg
	Dairy No. date of R &I fee	Dy. No 9460 dated 01-03-2019, Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ativan (0.5mg, 1mg, 2mg) tablet USFDA Approved
	Me-too-status	Lorazepam 2mg Tablets by M/s Heal Pharmaceuticals (Reg.#79397)
	GMP Status	Last GMP inspection conducted on 18-07-2018 and conclusion of inspection was: Based on the above facts the current compliance level is rated as good
	Remark of the Evaluator [XI]	• Fee is deposited on two deposit slips having No. 0829563 dated 01-03-2019 of Rs. 15000/- and 709570 dated 01-03-2019 of Rs. 5000/- • Undertaking at the end of form 5 is missing • The firm submitted letter No.F. 2-8/93-Lic (Vol-III) dated 25th June 2019 issued by Secretary Central Licensing Board showing Tablet (Psychotropic) (Amendents).
	Decision: Deferred for submission of undertaking.	
572.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi
	Brand Name + Dosage Form and Strength	T-One 1mg Tablet
	Composition	Each Tablet Contains: Lorazepam……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9461 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ativan (0.5mg, 1mg, 2mg) tablet USFDA Approved
	Me-too-status	Lorazepam 1mg Tablets by M/s Heal Pharmaceuticals (Reg.#79396)
	GMP Status	Last GMP inspection conducted on 18-07-2018 and conclusion of inspection was: Based on the above facts the current compliance level is rated as good

	Remark of the Evaluator [XI]	• Fee is deposited on two deposit slips having No. 0829564 dated 01-03-2019 of Rs. 15000/- and 709569 dated 01-03-2019 of Rs. 5000/- • Undertaking at the end of form 5 is missing • The firm submitted letter No.F. 2-8/93-Lic (Vol-III) dated 25th June 2019 issued by Secretary Central Licensig Board showing Tablet (Psychotropic) (Amendents)
	Decision: Deferred fot submission of undertaking.	
573.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi
	Brand Name + Dosage Form and Strength	Anax 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Alprazolam……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9454 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xanax (0.25mg, 0.5mg, 1mg, 2mg) tablets USFDA Approved
	Me-too-status	Lydia 1mg Tablets by M/s. Wilshire Laboratories (Reg#65699)
	GMP Status	Last GMP inspection conducted on 18-07-2018 and conclusion of inspection was: Based on the above facts the current compliance level is rated as good
	Remark of the Evaluator [XI]	• You have submitted the fee on two deposit slip slips having No. 0829555 dated 01-03-2019 of Rs. 15000/- and 709564 dated 01-03-2019 of Rs. 5000/-. The product name is mentioned on both the slips, however the strength on deposit slip No. 0829555 dated 01-03-2019 of Rs. 15000/- is 1gm while the strength mentioned on deposit slip No. 709564 dated 01-03-2019 of Rs. 5000/- is 1mg and the applied product is also 1mg tablet. The firm was asked for submission of differential fee for the applied product. In response the firm submitted undertaking that the said undertaking (No. 0829555 dated 01-03-2019 of Rs. 15000/-, 1gm) is used only for the applied product (Anax 1mg tablet) and they will not use it for any other product. • The firm submitted revised form 5 mentioned a single strength of 1mg both in form 5 and lable claim. • The firm revised the label claim from film coated to uncoated tablet along with submission of Rs. 5000/- on deposit slip No. 1901748 dated 02-09-2020. The revised label claim is as under: Each Tablet Contains: Alprazolam……1mg • Undertaking at the end of form 5 is missing • The firm submitted letter No.F. 2-8/93-Lic (Vol-III) dated 25th June 2019 issued by Secretary Central Licensig Board showing Tablet (Psychotropic) (Amendents)
	Decision: Deferred for submission of fresh fee challan with correct strength of applied formulation.	
574.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi

	Brand Name + Dosage Form and Strength	Anax 0.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Alprazolam……0.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9451 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xanax (0.25mg, 0.5mg, 1mg, 2mg) tablets USFDA Approved
	Me-too-status	Lydia 0.5mg Tablets by M/s Wilshire Laboratories (Reg#65705)
	GMP Status	Last GMP inspection conducted on 18-07-2018 and conclusion of inspection was: Based on the above facts the current compliance level is rated as good
	Remark of the Evaluator [XI]	• Fee is deposited on two deposit slips having No. 0829551 dated 01-03-2019 of Rs. 15000/- and 709563 dated 01-03-2019 of Rs. 5000/- • The firm revised the label claim from film coated to uncoated tablet along with submission of Rs. 5000/- on deposit slip No. 1901747 dated 02-09-2020. The revised label claim is as under: Each Tablet Contains: Alprazolam……0.5mg • Undertaking at the end of form 5 is missing • The firm submitted letter No.F. 2-8/93-Lic (Vol-III) dated 25th June 2019 issued by Secretary Central Licensig Board showing Tablet (Psychotropic) (Amendents)
	Decision: Deferred for submission of fresh fee challan with correct strength of applied formulation.	
575.	Name and address of manufacture / Applicant	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Brand Name + Dosage Form and Strength	Daxalta Capsule 40mg
	Composition	Each hard gelatin capsule contains: Duloxetine HCl (as delayed release pellets 20% w/w) eq to Duloxetine..……40mg Source: Alphamed Formulations Pvt. Ltd India
	Dairy No. date of R &I fee	Form-5 Dy.No 9626 dated 01-03-2019 Rs.100,000/- Dated 25-02-2019
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Duloxetine 40mg gastro-resistant capsules, MHRA Approved
	Me-too-status	Dulife 40mg capsules of M/s Evolution Pharmaceuticals (Reg. 091962)
	GMP Status	Panel inspection dated 10-01-2018 recommends grant of GMP certificate.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
576.	Name and address of manufacture / Applicant	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa

	Brand Name + Dosage Form and Strength	Daxalta Capsule 30mg
	Composition	Each hard gelatin capsule contains: Duloxetine HCl (as delayed release pellets 20% w/w) eq to Duloxetine.…30mg Source: Alphamed Formulations Pvt. Ltd India
	Dairy No. date of R &I fee	Dy.No 9625 dated 01-03-2019 Rs.100,000/- Dated 25-02-2019
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CYMBALTA (20mg, 30mg, 60 mg) delayed-release capsules USFDA Approved
	Me-too-status	Dulife 30mg capsules of M/s Evolution Pharmaceuticals (Reg. 091961)
	GMP Status	Panel inspection dated 10-01-2018 recommends grant of GMP certificate.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
577.	Name and address of manufacture / Applicant	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Brand Name + Dosage Form and Strength	Daxalta Capsule 60mg
	Composition	Each hard gelatin capsule contains: Duloxetine HCl (as delayed release pellets 20% w/w) eq to Duloxetine.…60mg Source: Alphamed Formulations Pvt. Ltd India
	Dairy No. date of R &I fee	Form-5 Dy.No 9627 dated 01-03-2019 Rs.100,000/- Dated 25-02-2019
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CYMBALTA (20mg, 30mg, 60 mg) delayed-release capsules USFDA Approved
	Me-too-status	Dulife capsules 60mg capsules of M/s Evolution Pharmaceuticals (Reg. 091963)
	GMP Status	Panel inspection dated 10-01-2018 recommends grant of GMP certificate.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
578.	Name and address of manufacture / Applicant	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Brand Name + Dosage Form and Strength	Daxalta Capsule 20mg
	Composition	Each hard gelatin capsule contains: Duloxetine HCl (as delayed release pellets 20% w/w) eq to Duloxetine.…20mg Source: Alphamed Formulations Pvt. Ltd India
	Dairy No. date of R &I fee	Form-5 Dy.No 9624 dated 01-03-2019 Rs.100,000/- Dated 25-02-2019
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's; As per SRO

	Approval status of product in Reference Regulatory Authorities	CYMBALTA (20mg, 30mg, 60 mg) delayed-release capsules USFDA Approved
	Me-too-status	Dulife 20mg capsules of M/s Evolution Pharmaceuticals (Reg. 091960)
	GMP Status	Panel inspection dated 10-01-2018 recommends grant of GMP certificate.
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
579.	Name and address of manufacture / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Lycenil Lotion 5% w/w
	Composition	Each gram of lotion contains: Permethrin…….50mg (5% w/w)
	Dairy No. date of R &I fee	Form-5 Dy.No 11255 dated 05-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Permethrin Lotion 5% w/w (MHRA Approved)
	Me-too-status	Plaveo Lotion by M/s Hiranis Pharmaceuticals (Reg.#76508)
	GMP Status	"GMP certificate issued on 03-07-2018."
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-16/2016-Lic dated 12th June 2017 from secretary central licensing board confirming Ceam/Ointment and Lotion section • The firm submitted undertaking at the end of form 5 duly signed by the technical persons
	Decision: Approved with change of brand name.	
580.	Name and address of manufacture / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Lutico Nasal Spray 50mcg/spray
	Composition	Each spray contains: Fluticasone Propionate…….50mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 11414 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Corticosteroids
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	120 sprays; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nasofan Allergy 50 microgram Nasal Spray Each 100 microlitre metered spray contains 50 microgram (mcg) of fluticasone propionate. MHRA Approved
	Me-too-status	Flexosone Nasal Spray by M/s Schazoo Laboratories (Reg.#40863)
	GMP Status	"GMP certificate issued on 03-07-2018."
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-16/2016-Lic dated 12th June 2017 from secretary central licensing board confirming Ceam/Ointment and Lotion section. Furthermore the firm informed that their product is lotion and for convenience of use, they packed it in a spray or dropper like bottle.

		• The firm deposited fee Rs. 5000/- on deposit slip No. 2049524 dated 01-09-2020 but did not revise the label claim as per reference formulation. The correct label claim as per reference formulation is "Each 100 microlitre metered spray contains 50 microgram (mcg) of fluticasone propionate"
	Decision: Deferred for following: • **Confirmation of required manufacturing facility for applied formulation.** • **Revision of label claim as per reference formulation.**	
581.	Name and address of manufacture / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form and Strength	Furamet nasal spray 50mcg/spray
	Composition	Each spray contains: Mometasone furoate as monohydrate…….50mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 11412 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Corticosteroids
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	60 sprays, 120 sprays, 140 sprays; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mometasone furoate 50 micrograms/actuation nasal spray, suspension MHRA Approved Each actuation (100 mg) contains 50 micrograms of mometasone furoate (as the monohydrate) as delivered dose (ex actuator).
	Me-too-status	Memocart nasal spray by M/s Platinum Pharma (Reg.#36585)
	GMP Status	"GMP certificate issued on 03-07-2018."
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-16/2016-Lic dated 12th June 2017 from secretary central licensing board confirming Ceam/Ointment and Lotion section. Furthermore the firm informed that their product is lotion and for convenience of use, they packed it in a spray or dropper like bottle. • The firm deposited fee Rs. 5000/- on deposit slip No. 2049523 dated 01-09-2020 but did not revise the label claim as per reference formulation. The correct label claim is "Each actuation (100 mg) contains 50 micrograms of mometasone furoate (as the monohydrate) as delivered dose (ex actuator)" • The reference formulation is a suspension nasal spray, while the master formulation of the applied formulation shows that it is a solution. The firm revised the master formulation as per reference formulation without submission of fee.
	Decision: Deferred for following: • **Confirmation of required manufacturing facility for applied formulation.** • **Revision of label claim as per reference formulation.**	
582.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Icare 40mg dry powder Injection

	Composition	Each vial contains: Omeprazole (as Sodium) ……..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15039 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial (TGA Approved)
	Me-too-status	Prisma 40mg IV Injection by M/s Rasco Pharma (Reg#82762)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for consideration on its turn.	
583.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Engferol Injection 5mg/ml Oral/IM
	Composition	Each ml contains: Cholecalciferol (vitamin D3)…….5mg (200,000IU)
	Dairy No. date of R &I fee	Form-5 Dy.No 11458 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019
	Pharmacological Group	Vitamin D3 analogue
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	1mlx1's; 1mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU/1ml oral solution in ampoule (ANSM France approved) Vitamin D3 Good 200,000 IU/1ml IM solution for injection (ANSM France approved)

	Me-too-status	D-Rick Injection by Caliph Pharmaceuticals (Pvt.) Ltd, (Reg#82563)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation • The firm informed that they are using asceptic technique for filling so need no terminal sterilization process.
	Decision: Deferred for submission of undertaking.	
584.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Escare 40mg dry powder Injection
	Composition	Each vial contains: Esomeprazole (as Sodium)……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15038 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole 40mg Powder for Solution for Injection/Infusion MHRA Approved
	Me-too-status	Esobrain Injection 40mg by M/s WinBrains Research Laboratories, (Reg#85072)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.

		Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for consideration on its turn.	
585.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Anzifur Injection 100mg/5ml
	Composition	Each 5ml contains: Iron sucrose complex eq to elemental iron……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11459 dated 05-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Anti-anaemic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer (50mg/2.5mL, 100mg/5mL, 200mg/10mL) (20mg/mL) in single-dose vials. Injection USFDA Approved
	Me-too-status	Irofit Injection 100mg/5ml by M/s Zafa Pharma (Reg#82291)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing

		• The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for clarification regarding use type of primary packaging material for applied formulation and submission of undertaking.	
586.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Kanprazole 40mg dry powder Injection
	Composition	Each vial contains: Pantoprazole (as Sodium sesquihydrate) ……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 15040 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40mg Powder for Solution for Injection MHRA Approved
	Me-too-status	Panpak 40mg IV Injection by M/s Rasco Pharma (Reg#82763)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation • The firm did not submitted revised master formulation adjusting the weight of API considering the hydrated form
	Decision: Deferred for consideration on its turn.	
587.	Name and address of manufacture / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Rawalpindi. ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore

	Brand Name + Dosage Form and Strength	Anzi-Cilin 4.5g Dry Powder Injection
	Composition	Each Vial Contains: Piperacillin (as Sodium)……..4g Tazobactam (as Sodium)……..0.5g
	Dairy No. date of R &I fee	Form-5 Dy.No 11460 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	50ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam, 4gm/0.5gm) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tacip 4.5gm Injection by M/s Macter Int. (Reg#73632)
	GMP Status	M/s Kanel Pharma was inspected on 06-03-2019 and recommendations of inspection was: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 has been submitted by the applicant duly signed by the signatory • The firm did not submit undertaking at the end of form 5 • A copy of contract manufacturing agreement between M/s Kanel Pharma and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 05 approved sections of applicant. i.e. M/s Kanel Pharma • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 09 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for clarification regarding type of primary packaging material for applied formulation and submission of undertaking.	
588.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Eyrin Forte Tablets 275mg/150mg/75mg
	Composition	Each Tablet Contains: Ethambutol HCl…….275mg Rifampicin…….150mg Isoniazid…….75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12417 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	80's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rifampicin/Isoniazid/Ethambutol hydrochloride 150mg/75mg/275mg film coated Tablets (WHO Approved formulation)

	Me-too-status	Myrin Forte Tablet by M/s Wyeth Pakistan (Reg. No. 75891)
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revise the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5. • The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposit slip No. 2037971 date 28-08-2020. The revised label claim is as under: Each film coated Tablet Contains: Ethambutol HCl…….275mg Rifampicin…….150mg Isoniazid…….75mg
	Decision: Deferred for consideration on its turn.	
589.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Eyrin-P forte Tablets 275mg/150mg/75mg/400mg
	Composition	Each Film Coated Tablet Contains: Ethambutol HCl……275mg Rifampicin……150mg Isoniazid……...…75mg Pyrazinamide……400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12419 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10x8's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rifampicin 150 mg/ Isoniazid 75 mg/ Pyrazinamide 400 mg/Ethambutol Hydrochloride 275 mg film coated Tablets (WHO Approved formulation)
	Me-too-status	Myrin P Forte Tablets by M/s Pfizer Pakistan Ltd (Reg#027082)
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5.
	Decision: Deferred for consideration on its turn.	
590.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Eyrin-P Tablets 225mg/120mg/60mg/300mg

	Composition	Each Tablet Contains: Ethambutol HCl……225mg Rifampicin……120mg Isoniazid……60mg Pyrazinamide……300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12418 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting along with weblink. • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for consideration on its turn.	
591.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Eyrin Tablets 300mg/150mg/75mg
	Composition	Each Tablet Contains: Ethambutol HCl……300mg Rifampicin……150mg Isoniazid……75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12416 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rifampicin/Isoniazid/Ethambutol hydrochloride 150mg/75mg/275mg film coated Tablets (WHO Approved formulation)
	Me-too-status	Myrin Tablets by M/s Pfizer Pakistan Ltd (Reg#009968)
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.

	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5. • The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposite slip No. 2037972 date 28-08-2020. The revised label claim is as under: Each film coated Tablet Contains: Ethambutol HCl……300mg Rifampicin……150mg Isoniazid……75mg • However the firm did not corrected the strength in case of Ethambutol HCl in label claim as per reference formulation.
	Decision: Deferred for consideration on its turn.	
592.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Pirazin Tablet 500mg
	Composition	Each Tablet Contains: Pyrazinamide……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12421 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Other drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	500's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pyrazinamide 500 mg uncoated Tablets (WHO Approved formulation)
	Me-too-status	PZ tablets 500mg by M/s Bio-Mark Pharmaceuticals (Reg#093976)
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5.
	Decision: Deferred for consideration on its turn.	
593.	Name and address of manufacture / Applicant	M/s ICI Pakistan Limited. S-33, Hawksbay, S.I.T.E, Karachi
	Brand Name + Dosage Form and Strength	Lederrif INH 150 Tablet
	Composition	Each Tablet Contains: Rifampicin……150mg Isoniazid……75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12420 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	30's, 48's, 100's, 500's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rifampicin/Isoniazid 150mg/75mg film-coated Tablets (WHO Approved formulation)

	Me-too-status	Rin 150mg/75mg Tablet by M/s Wyeth Pakistan Ltd (Reg. No. 073790)
	GMP Status	Last GMP inspection was conducted on 25-01-2018 and conclusion of inspection was; Based on the areas inspected, the people met and the documents reviewed and considering the findings of inspection M/s ICI Pakistan Ltd Kasur was considered to be GMP compliant with reference to GMP guidelines as per Drugs Act, 1976 and rules framed there under.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per prescribed format duly signed by authorized person and submitted original documents and undertaking at the end of form 5. • The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposit slip No. 2037973 date 28-08-2020. The revised label claim is as under: Each film coated Tablet Contains: Rifampicin……150mg Isoniazid……75mg The master formulation is submitted of different strength
	Decision: Deferred for consideration on its turn.	
594.	Name and address of manufacture / Applicant	M/s. Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase III, Industrial Estate Hattar.
	Brand Name + Dosage Form and Strength	Etipro Capsule 40mg
	Composition	Each Capsule Contains: Omeprazole (as enteric coated pellets 8.5% w/w)……40mg Source: Precise Chemipharma Pvt. Ltd India
	Dairy No. date of R &I fee	Dy.No 12423 dated 06-03-2019 Rs.100,000/- Dated 06-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec 40 mg hard gastro-resistant capsules MHRA Approved
	Me-too-status	Gosoft Capsule 40mg by M/s Bio-Mark Pharmaceuticals (Reg. No. 85700)
	GMP Status	Last GMP inspection was conducted on 07-05-2018 and conclusion of inspection was; Overall the firm was operating under good level of cGMP
	Remark of the Evaluator [XI]	• The reply is submitted by M/s ICI Pakistan Limited. ICI House, 5 West Wharf, Karachi. The firm informed that the management of firm changed from Cirin Pharmaceuticals to ICI Pakistan Ltd and attached letter No. f.3-42/92-Lic (Vol-III) (Pt) dated 18-02-2020 issued by secretary Central Licensing Board. • The firm submitted valid GMP certificate of supplier of pellets Precise Chemipharma Pvt. Ltd India valid upto 27-02-2022. • The COA and submitted stability study data shows omeprazole enteric coated pellets 8.5% w/w while the list of products attached with GMP certificate doesnot contain omeprazole enteric coated pellets.

		• The firm submitted stability study data of three batches from the supplier of pellets as per Requirements of Registration Board decision of 293rd meeting but not as per Zone IV-A.
	Decision: Deferred for consideration on its turn.	
595.	Name and address of manufacture / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 5mg/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……...5mg Olmesartan Medoxomil…….40mg
	Dairy No. date of R &I fee	Dy.No 12199 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 5mg /40mg of M/s Searle Pakistan (Reg#076188)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Remark of the Evaluator [XI]	• Firm submitted all documents as required in enclosure of form 5.
	Decision: Deferred for consideration on its turn.	
596.	Name and address of manufacture / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 5/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……..…5mg Olmesartan Medoxomil……..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12198 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 5/20mg of M/s Searle Pakistan (Reg#076187)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019.
	Remark of the Evaluator [XI]	• Firm submitted all documents as required in enclosure of form 5.
	Decision: Deferred for consideration on its turn.	
597.	Name and address of manufacture / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Olmem 10/20mg Tablet

	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……..…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12200 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Innovator's specification
	Pack size and Demand Price	20's, 28's, 30's, 56's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor (5mg /20mg, 10mg /20mg, 5mg /40mg, 10mg /40mg) film coated tablets of (USFDA Approved)
	Me-too-status	Olesta-AM 10/20mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Remark of the Evaluator [XI]	• Firm submitted all documents as required in enclosure of form 5.
	Decision: Deferred for consideration on its turn.	
598.	Name and address of manufacture / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Smval 5/80mg Tablets
	Composition	Each Tablet Contains: Amlodipine besylate……..…5mg Valsartan……..…80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12195 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Remark of the Evaluator [XI]	• The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposite slip No. 0766456 date 02-09-2020. The firm also corrected the salt form of amlodipine in label claim as per reference formulation without considering the salt factor. The revised label claim is as under: Each film coated Tablet Contains: Amlodipine (as besylate) ……..…5mg Valsartan……..…80mg • Firm submitted all documents as required in enclosure of form 5.
	Decision: Deferred for consideration on its turn.	
599.	Name and address of manufacture / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Smval 5/160mg Tablets

	Composition	Each Tablet Contains: Amlodipine besylate……5mg Valsartan…….160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 12196 dated 06-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x14's, 2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP Status	GMP certificate issued to M/s Sapient Pharma Lahore base on inspection conducted on 18-11-2019
	Remark of the Evaluator [XI]	• The firm revise the label claim from uncoated to film coated tablets along with submission of Rs. 5000/- on deposite slip No. 0766489 date 02-09-2020. The firm also corrected the salt form of amlodipine in label claim as per reference formulation without considering the salt factor. The revised label claim is as under: Each film coated Tablet Contains: Amlodipine (as besylate) ……5mg Valsartan……..…160mg • Firm submitted all documents as required in enclosure of form 5.
	Decision: Deferred for consideration on its turn.	
600.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar. ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefial Capsule 400mg
	Composition	Each Capsule Contains: Cefixime monohydrate eq to Cefixime…400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14937 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX capsules 400mg, (USFDA approved)
	Me-too-status	Xalfocin 400mg Capsule by Martin Dow Karachi (Reg. 80646)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the

		SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing
	Decision: Deferred for consideration on its turn.	
601.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefial 100mg/5ml Dry Suspension
	Composition	Each 5ml contains: Cefixime Trihydrate eq to Cefixime……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14940 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefixime 100mg/5ml Powder for Oral Suspension MHRA Approved
	Me-too-status	Fix 100mg/5ml Suspension by M/s Aptcure (Pvt) Ltd (Reg. 85229)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder

		Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • Fee of Rs. 50000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing
	Decision: Deferred for consideration on its turn.	
602.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 1g Injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…….1g
	Dairy No. date of R &I fee	Form-5 Dy.No 14939 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin 1g Powder for solution for injection or infusion MHRA Approved
	Me-too-status	Ceftro Injection 1gm IV by Biocef (Pvt) Ltd, (Reg. No. 82740)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • The firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by the technical persons

		• Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However, the deposit slip contains both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container.
	Decision: Deferred for consideration on its turn.	
603.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 500mg injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14936 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg powder for solution for injection MHRA Approved
	Me-too-status	Ceftro Injection 500mg IV by Biocef (Pvt) Ltd, (Reg. No. 82738)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.
	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder

		Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • The firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by the technical persons • Fee of Rs. 50000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However the deposit slip contain both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container
	Decision: Deferred for consideration on its turn.	
604.	Name and address of manufacture / Applicant	M/s Athan Pharmaceuticals Plot 84/1, Block B, Phase 5, Industrial Estate Hattar ***Contract Manufactured by:*** M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form and Strength	Cefixon 250mg injection IV
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 14938 dated 07-03-2019 Rs.50,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin 250mg Powder for solution for injection MHRA Approved
	Me-too-status	Ceftro Injection 250mg IV by Biocef (Pvt) Ltd, (Reg. No. 82737)
	GMP Status	Issuance of DML to M/s Athan Pharmaceuticals Hattarin 269th Meeting of CLB dated 05-03-2019. Last GMP inspection of M/s Aulton Pharmaceuticals Hattar was conducted on 27-06-2019 and conclusion of inspection was: As per observations made during inspection, the manufacturing, quality control and environmental facilities, provided the qualified staff employed, the documentation maintained, implementation of the SOP's the GMP compliance status of the firm M/s Aulton Pharma is found to be satisfactory.

	Remark of the Evaluator [XI]	• The firm submitted letter No. F. 1-17/2013-Lic dated 11th April 2017 issued by Secretary Central Licensig Board showing that M/s Aulton Pharmaceuticals have Capsule section (Cephalosporin), Dry Powder Suspension Section (Cephalosporin) and Dry Powder Injection Section (Cephalosporin) • The firm submitted duly filled form 5 signed by the signatory and undertaking at the end of form 5 signed by the technical persons • Fee of Rs. 50,000/- submitted by manufacturer M/s Aulton Pharmaceuticals and not the applicant M/s Athan Pharmaceuticals. The firm informed that it was clerical mistake to deposit the fee on deposit slip of M/s Aulton Pharmaceuticals and they requested to consider it on account of M/s Athan Pharmaceuticals. However the deposit slip contain both the name of M/s Aulton Pharmaceutical and its DML No. 000828. • A copy of contract manufacturing agreement between M/s Athan Pharmaceuticals and M/s Aulton Pharmaceuticals is submitted • The firm submitted list of 08 approved sections of applicant. i.e. M/s Athan Pharmaceuticals • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 05 applied products for contract manufacturing • The firm did not mentioned type of primary packaging material of applied formulation whether it is type I, II or III glass container • The firm did not submit master formulation for the applied product.
	Decision: Deferred for consideration on its turn.	
605.	Name and address of manufacture / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Pipetazo 4.5g Injection
	Composition	Each Vial Contains: Piperacillin (as Sodium)……..4g Tazobactam (as Sodium)……..0.5g
	Dairy No. date of R &I fee	Form-5 Dy.No 17419 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam, 4gm/0.5gm) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tacip 4.5gm Injection by M/s Macter Int. (Reg#73632)
	GMP Status	M/s Rotex Pharma Islamabad was inspected on 19-09-2018 and recommendations of inspection was: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the

		Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm did not possess required machinery and equipments for said purpose. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Rotex Pharma Pvt Ltd. along with undertaking at the end of form 5. • A copy of contract manufacturing agreement between M/s Rotex Pharma Pvt Ltd and M/s English Pharmaceuticals Industries is submitted • The firm submitted list of 29 approved sections of applicant. i.e. M/s Rotex Pharma Pvt Ltd. • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 04 applied products for contract manufacturing • The firm mentioned the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for consideration on its turn.	
606.	Name and address of manufacture / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad ***Contract Manufactured By:*** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Pipetazo 2.25g Injection
	Composition	Each Vial Contains: Piperacillin (as Sodium)…..……..2g Tazobactam (as Sodium)……0.25g
	Dairy No. date of R &I fee	Form-5 Dy.No 17416 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Pharmacological Group	Penicillin and beta-lactamase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN (piperacillin and tazobactam, 2gm/0.25gm) for injection, for intravenous use. **USFDA** approved
	Me-too-status	Tanzo Injection by M/s Bosch Pharmaceutical (Reg. No. 39593)
	GMP Status	M/s Rotex Pharma Islamabad was inspected on 19-09-2018 and recommendations of inspection was: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm did not possess required machinery and equipments for said purpose. Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.
	Remark of the Evaluator [XI]	• Form 5 submitted by the applicant i.e. M/s Rotex Pharma Pvt Ltd. along with undertaking at the end of form 5. • A copy of contract manufacturing agreement between M/s Rotex Pharma Pvt Ltd and M/s English Pharmaceuticals Industries is submitted

		• The firm submitted list of 29 approved sections of applicant. i.e. M/s Rotex Pharma Pvt Ltd. • The firm informed that they don't have any product registered/approved on contract manufacturing • The firm submitted list of 04 applied products for contract manufacturing • The firm mentioned the use of type I glass container as primary packaging material of applied formulation
	Decision: Deferred for consideration on its turn.	

Deferred cases (Human):

607.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Falcon 120mg powder for Injection
	Composition	Each Vial Contains: Artesunate ..……120mg
	Dairy No. date of R &I fee	Dy.No 40278 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antimalarial
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved injectable artesunate 120mg (WHO Approved formulation)
	Me-too-status	Gen-M 120mg Injection of M/s Genix Pharma (Pvt) Ltd. (Reg.#76073)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.
	Remark of the Evaluator [XI]	• Firm submitted complete manufacturing outline along with use of type I glass container as primary packaging container
	Previous Decision (295-DRB)	• Deferred for confirmation of manufacturing facility
	Evaluation by PEC	• The firm submitted letter No.F.3-1/97-Lic (M-181) dated 30th January 2004 confirming the approval of injectable (powder) section
	Decision: Approved.	
608.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Falcon 60mg powder for Injection
	Composition	Each Vial Contains: Artesunate …….60mg
	Dairy No. date of R &I fee	Dy.No 40276 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antimalarial
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved injectable artesunate 60mg (WHO Approved formulation)
	Me-too-status	Misonate 60mg Injection of M/s Tabros Pharma (Pvt.) Ltd. (Reg.# 57719)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.

	Remark of the Evaluator [XI]	• Firm submitted complete manufacturing outline along with use of type I glass container as primary packaging container
	Previous Decision (295-DRB)	• Deferred for confirmation of manufacturing facility
	Evaluation by PEC	• The firm submitted letter No.F.3-1/97-Lic (M-181) dated 30th January 2004 confirming the approval of injectable (powder) section
	Decision: Approved.	
609.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Pyrol -T Plus 37.5/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol….....37.5mg Paracetamol…….325mg
	Dairy No. date of R &I fee	Dy.No 39610 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10’s, 20’s, 30’s; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Distalgesic Tablets by M/s Atco Lab., (Reg#73865)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm has submitted correct label claim as per reference formulation without submission of applicable fee. The correct label claim is; Each Film Coated Tablet Contains: Tramadol HCl ....…37.5mg Paracetamol…..325mg Moreover the firm adjusted the weight of API in master formulation considering the salt factor. • The firm submitted revised form 5 duly signed by the qualified persons on the undertaking
	Previous Decision (295-DRB)	• Deferred for submission of applicable fee for correction of label claim
	Evaluation by PEC	• The firm submitted Rs. 5000/- on deposite slip No. 2032819 dated 17-08-2020 for correction of label claim
	Decision: Approved.	
610.	Name and address of manufacture / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Azal Eye Drops 1%
	Composition	Each ml contains: Azithromycin…..1% (10mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 6348 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Macrolide Antibiotic
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azasite 1% sterile opthalmic solution USFDA approved.

	Me-too-status	Kraze Opthalmic solution 10mg/ml by M/s Meidcaids (Reg#082125)
	GMP Status	Firm was inspected on 20-12-2017 and Conclusion of inspection was: Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (pvt.) ltd., is operating satisfactory. **Overall hygienic condition of the firm was satisfactory at the time of inspection** however, they were advised to continue improvements in production and quality control, they agreed."
	Remark of the Evaluator [XI]	• Submit revised form 5 as per approved formate (signatory alongwith some text is missing) • You have not submit master formulation. Submit complete master formulation
	Previous Decision (295-DRB)	• Deferred for submission of Form 5 as per approved format along with master formulation.
	Evaluation by PEC	• The firm submitted revised form 5 as per prescribed format along with master formulation of the applied product
	Decision: Approved with innovator's specifications.	
611.	Name and address of manufacture / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Hypersal Eye Drops 5%
	Composition	Each ml contains: Sodium chloride……5%
	Dairy No. date of R &I fee	Form-5 Dy.No 6342 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Other ophthalmologicals
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	5ml; 10ml; 15ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	OPTRINE FORET HYPERTONIC SALINE EYE DROPS sodium chloride 50mg/mL topical liquid bottle (TGA Approved)
	Me-too-status	Sodium Chloride 5% Ophthalmic Solution by M/s Opal Labs (Reg#48483)
	GMP Status	Firm was inspected on 20-12-2017 and Conclusion of inspection was: Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (pvt.) ltd., is operating satisfactory. **Overall hygienic condition of the firm was satisfactory at the time of inspection** however, they were advised to continue improvements in production and quality control, they agreed."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 but not as per approved formate • The firm submitted master formulation of the applied
	Previous Decision (295-DRB)	• Deferred for submission of application on prescribed Form 5.
	Evaluation by PEC	• The firm submitted revised form 5 as per prescribed format
	Decision: Approved.	
612.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore

	Brand Name + Dosage Form and Strength	Side 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4111 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride 200mg Tablets (MHRA Approved)
	Me-too-status	Amiride Tablet 200mg by M/s Shrooq Pharmaceuticals (Pvt) Ltd (Reg#063102)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted the 1st page of form 5 duly signed by the signatory.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved.	
613.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 6.25mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol……6.25mg
	Dairy No. date of R &I fee	Dy.No 4104 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 6.25 mg film-coated tablet USFDA Approved
	Me-too-status	Hidilol 6.25mg Tablets by M/s Helix Pharma (Reg#53014)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved.	

614.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 3.125mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol……3.125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4103 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 3.125mg film-coated tablet USFDA Approved
	Me-too-status	Carlov 3.125mg Tablet by M/s Hilton Pharma (Reg#36423)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved.	
615.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 12.5mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol…..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4105 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 12.5mg film-coated tablet USFDA Approved
	Me-too-status	Hidilol 12.5mg Tablets by M/s Helix Pharma (Reg#50365)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•

	Decision: Approved.	
616.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Metfin 500mg Tablets
	Composition	Each Film Coated Tablet Contains: Metformin HCl…..500mg
	Dairy No. date of R &I fee	Dy.No 4120 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Biguanide (Antidiabetic)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metformin 500mg film coated Tablets (MHRA Approved)
	Me-too-status	Glucomin 500mg Tablet by M/s Lisko Pakistan (Reg#82146)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved.	
617.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 50mg
	Composition	Each Capsule Contains: Pregabalin……..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4107 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 50mg capsules USFDA approved
	Me-too-status	Gabica 50mg Capsule by M/s Getz Pharma (Reg#48725)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.

		• Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved with innovator's specifications.	
618.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 100mg
	Composition	Each Capsule Contains: Pregabalin……...100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4109 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA 100mg Capsules USFDA Approved
	Me-too-status	Gabica 100mg Capsule by M/s Getz Pharma (Reg#47366)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved with innovator's specifications.	
619.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 75mg
	Composition	Each Capsule Contains: Pregabalin…..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4108 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA 75mg Capsules USFDA Approved
	Me-too-status	Gabica 75mg Capsule by M/s Getz Pharma (Reg#47365)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends

		grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved with innovator's specifications.	
620.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Tamsin 0.4mg Capsule
	Composition	Each modified release Capsule Contains: Tamsulosin HCl (as SR pellets 0.2%).....0.4mg (Source of Pellets: Vision Pharma)
	Dairy No. date of R &I fee	Form-5 Dy.No 4115 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamurex 400 micrograms prolonged-release capsules (MHRA approved)
	Me-too-status	Timsol 0.4 mg Capsule by M/s Scilife Pharma (Reg#82094)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The firm submitted GMP Certificate of supplier of pellets (Vision Pharma) which expired on 25.01.2019
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement and GMP Certificate of supplier of pellets (Vision Pharma).
	Evaluation by PEC	• The firm submitted 1st page of Form 5 duly signed by the signatory along with valid GMP certificate of supplier of pellets (Vision Pharma) valid upto 10th February 2022.
	Decision: Approved.	
621.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Zip 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Zolmitriptan……5mg

	Dairy No. date of R &I fee	Form-5 Dy.No 4101 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 5mg film coated tablets MHRA Approved
	Me-too-status	Zolmiton 5mg tablets of M/s CKD Pharmaceuticals (Reg#081786)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The manufacturer have claimed manufacturer's specifications while the official monograph is present in USP.
	Previous Decision (295-DRB)	• Deferred for signatures as per requirement
	Evaluation by PEC	•
	Decision: Approved.	

Case no. 02 Registration applications for local manufacturing of (Veterinary) drugs

a. New cases

622.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"
	Brand Name + Dosage Form and Strength	Coxnil E Oral Solution 500mg/ml
	Composition	Each ml contains: Amprolium.….500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6210 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anticoccidial Agent
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	500ml; 1L; 2.5L; Decontrolled
	Me-too-status	
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm replied that evidence of applied formulation/drug already approved by DRAP is not available but it is available internationally with name of Amprolium 50% oral solution, "KEPRO", Netherland
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
623.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"

	Brand Name + Dosage Form and Strength	Coxnil E Oral Solution 200mg/ml
	Composition	Each ml contains: Amprolium.…200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6209 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anticoccidial Agent
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	500ml; 1L; 2.5L; Decontrolled
	Me-too-status	Hi-Amprol Oral Solution by M/s Selmore Pharmaceuticals (Reg#046501)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm was asked for correction of label claim in Form 5 from Each ml contains: Amprolium…200mg to Each ml contains: Amprolium as HCl…200mg to mention the salt form as per available label claim of me-too product. • The firm replied that they have mentioned Amprolium as HCl…200mg in the label without submission of fee and provide evidence of submitted label.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
624.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"
	Brand Name + Dosage Form and Strength	Doramax Injection 10mg/ml
	Composition	Each ml contains: Doramectin..……..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6211 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antiparasitic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	100ml; Decontrolled
	Me-too-status	Dora Injection by M/s Wimits Pharmaceuticals (Reg#088615)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm inform that product will be terminally sterilized after filling in the sterile area.
	Decision: Approved with innovator's specifications.	
625.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"
	Brand Name + Dosage Form and Strength	Elvomec Super Gold Injection 100ml pack
	Composition	Each ml contains: Ivermectin……..20mg (2%) Clorsulon……..10mg (1%)
	Dairy No. date of R &I fee	Dy.No 6208 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antiparasitic and anthelmintic
	Type of form	Form 5

	Finished product specifications	USP
	Pack size and Demand Price	100ml; Decontrolled
	Me-too-status	Ivoclor Injection by M/S Nawal Pharmaceuticals (Reg#078244)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm inform that product will be terminally sterilized after filling in the sterile area.
	Decision: Approved.	
626.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"
	Brand Name + Dosage Form and Strength	Elvomec Super Gold Injection 10ml pack
	Composition	Each ml contains: Ivermectin…..20mg Clorsulon…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7714 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antiparasitic and anthelmintic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; Decontrolled
	Me-too-status	Ivoclor Injection by M/S Nawal Pharmaceuticals (Reg#078244)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm inform that product will be terminally sterilized after filling in the sterile area.
	Decision: Approved.	
627.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"
	Brand Name + Dosage Form and Strength	Elvomec Super Gold Injection 50ml pack
	Composition	Each ml contains: Ivermectin…..20mg Clorsulon…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7715 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antiparasitic and anthelmintic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	50ml; Decontrolled
	Me-too-status	Ivoclor Injection by M/S Nawal Pharmaceuticals (Reg#078244)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm inform that product will be terminally sterilized after filling in the sterile area.
	Decision: Approved.	
628.	Name and address of manufacture / Applicant	"M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi"

	Brand Name + Dosage Form and Strength	Elvomec Super Gold Injection 200ml pack
	Composition	Each ml contains: Ivermectin……...20mg Clorsulon…….10mg
	Dairy No. date of R &I fee	Dy.No 7716 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antiparasitic and anthelmintic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	200ml; Decontrolled
	Me-too-status	Ivoclor Injection by M/S Nawal Pharmaceuticals (Reg#078244)
	GMP Status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remark of the Evaluator [XI]	• The firm inform that product will be terminally sterilized after filling in the sterile area.
	Decision: Approved.	
629.	Name and address of manufacture / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Ketox-T LA Injection
	Composition	Each ml contains: Oxytetracycline……..…200mg Ketoprofen……...30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5961 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibiotic, NSAID
	Type of form	Form 5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	50ml; As per SRO
	Me-too-status	Oxyfen LA Injection By M/s Selmore Pharmaceutical (Reg#071091)
	GMP Status	The firm was inspected on 16-07-2019 and conclusion of inspection was: Keeping in view the above stated observations during inspection areas visited, documents reviewed and people met it is concluded that the firm M/s Inshal Pharmaceutical Rawat has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections.
	Remark of the Evaluator [XI]	• The firm submitted incorrect undertaking at the end of form 5 • The firm submitted the use of type II glass container as primary packaging material of applied formulation
	Decision: Deferred for clarification of type of primary packaging material for applied formulation and submission of correct undertaking.	
630.	Name and address of manufacture / Applicant	M/s Univet Pharmaceuticals. 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name + Dosage Form and Strength	Avilamix 10% Powder
	Composition	Each 100g contains: Avilamycin……10g

	Dairy No. date of R &I fee	Form-5 Dy.No 8806 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antibiotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	HDPE Jars 100g, 500g, 1kg, 2.5kg, 5kg, 10kg, 20kg, 25kg; As per SRO
	Me-too-status	
	GMP Status	The firm was inspected on 26/10/2017 and conclusion of inspection was: The firm is working at good level of GMP compliance as of today
	Remark of the Evaluator [XI]	• The firm submitted undertaking at the end of form 5 duly signed by the technical persons • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) contains different ingredients (Avilamycin Activity 100gms, Soybean Mill Run 900gms) than applied product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too) alongwith registration number, brand name and name of firm.	

b. Deferred cases (Veterinary):

631.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	AMI-HANS ORAL LIQUID
	Composition	Each 100ml contains:- Doxycycline HCl …… 20g Tylosin tartrate ……..…. 10g Guaifenesin ….…… 20g Aminophylline …… 8g
	Diary No., Date of R & I & Fee	Dy.No 1529 dated 14/02/2020; Rs. 20,000 14/02/2020
	Pharmacological Group	Antibiotic, Expectorant, Bronchodilator
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre; Decontrolled
	Me-Too Status	Tyco-G Oral Liquid by M/s Attabak Pharmaceuticals (Reg#075704)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Remarks of Evaluator	• The firm has not revised the label claim as per approved Mee-Too product alongwith submission of applicable fee. The strength of molecules of the applied product is different as compared to approved Mee-Too product. • The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision (294-DRB)	• Deferred for revision of formulation as per DRAP approved me-too / generic product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised the formulation (corrected the strength of molecule in label claim) as per DRAP approved me-too / generic product along with submission of Rs 20,000/- on deposit slip No. 2028350 dated 24-08-2020. The firm also submitted the requisite documents as per enclosure of form 5.
	Decision: Approved with innovator's specifications.	

Case no. 03 Registration applications for local manufacturing of (Human-Covid) drugs

a. New cases

Priority approval of Azithromycin:

In continuation to Authority‟s letter NO. F.76-DRAP/2020(PE&R) dated 5th May, 2020, Drug Regulatory Authority of Pakistan in its 77th meeting held on 7th April, 2020 has also approved the formulation of Azithromycin in the list of drugs/formulations for priority approval/registeration during COVID-19 pandemicalong with other drugs.

1.Azithromycin Tablet 500mg:

Composition: Each Film coated tablet contains: Azithromycin as dihydrate…….500mg
Availability in RRAs: Azithromycin 500mg Film-Coated Tablets MHRA Approved
Me too status: Azithrolide 500mg Tablet by M/s Heal Pharma (Reg # 084234)
Specifications: USP

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
632.	M/s Ameer Pharma. 23 KM-Sheikhupura Road, Lahore	Azomeer 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…. …500mg	Form-5 Dy.No 15112 dated 29-06-2020 Rs.20,000/- Dated 29-06-2020	3's, 6's, 7's, 10's, 14's, 20's, 28's, 30's; As per SRO	The firm was inspected on 9-12-2019 and 26-01-2020 and panel recommends renewal of DML	**Approved.**
633.	M/s Metro Pharmaceuticals. Plot # 14, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi	Otisthro 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 15804 dated 02-07-2020 Rs.20,000/- Dated 02-07-2020	6's, 12's; As per SRO	Last inspection report dated 17/05/2019, and panel recommends renewal of DML.	**Approved.**
634.	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi	Azithro 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate) …….500mg	Form-5 Dy.No 15177 dated 29-06-2020 Rs.20,000/- Dated 29-06-2020	1x6's, 1x3's; As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.	**Approved.**
635.	M/s Rasco Pharma. 5.5 Km, Raiwind Road, Lahore	Az-Ko 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)…500mg	Form-5 Dy.No 15045 dated 26-06-2020 Rs.20,000/- Dated 26-06-2020	6's; As per SRO	The firm was inspected on 04-02-2019 and panel recommends renewal of DML	**Approved.**
636.	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif	Azidose 500mg Tablet	Each Film Coated Tablet Contains:	Form-5 Dy.No 14222 dated 19-06-2020 Rs.20,000/-	1x6's, 1x3's; As per SRO	Last inspection report dated 18-10-2019	**Approved.**

			Azithromycin as Dihydrate….. 500mg	Dated 19-06-2020		concluded that the firm was considered to be operating at satisfactory level of cGMP.	
637.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad	Hyzith 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)…..500mg	Form-5 Dy.No 13951 dated 17-06-2020 Rs.20,000/- Dated 17-06-2020	6's; As per SRO	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate	**Approved.**
638.	M/s Munawar Pharma Pvt Ltd. 31 Km, Ferozepur Road, Lahore	M-Zith 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Form-5 Dy.No 13956 dated 17-06-2020 Rs.20,000/- Dated 17-06-2020	10's; As per SRO	GMP certificate issued based on inspection dated 07-11-2017 The firm revised the label claim from uncoated to film coated tablets along with submission of Rs 5000/- on deposit slip No.2026335 dated 31-08-2020	**Approved.**
639.	M/s Mafins Pharma. Plot No. A-5, S.I.T.E, Super Highway Industrial Area, Karachi	Azi-M 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 14298 dated 22-06-2020 Rs.20,000/- Dated 22-06-2020	1x6's; As per SRO	The firm was inspected on 05-10-2017 representing good level of GMP. You have applied for film coated tablets but master	**Deferred for clarification of manufacturing outline for applied formulation.**

						formulation and manufacturing outline doesn't show coating composition and coating procedure respectively, clarify?	
640.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK	Azor 500mg film coated Tablet	Each film coated Tablet Contains: Azithromycin as dihydrate…. …500mg	Form-5 Dy.No 11426 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	1x6's; As per SRO	The firm applied on prescribed form 5 for the product along with undertaking at the end of form 5. The firm revised the label claim from uncoated to film coated tablets without submission of applicable fee. Latest GMP inspection report not submitted Justification for addition of 2% overage	**Deferred for revision of formulation as per reference product. Submission of applicable fee, GMP status during last 3 years and justification of using overage.**
641.	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad	Karzit-Forte 500mg tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)…500mg	Form-5 Dy.No 17876 dated 22-07-2020 Rs.20,000/- Dated 22-07-2020	2's, 3's, 4's, 6's, 10x6's 10x3's 10's, 12's; As per SRO	Firm was inspected on 17-12-2019 and conclusion was: basic elements of GMP compliance reference to schedule B-II are in place and complied with.	**Approved.**

642.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Maczin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 17871 dated 22-07-2020 Rs.20,000/- Dated 22-07-2020	6's; As per SRO	GMP certificate issued to the firm based on inspection conducted on 02-10-2019	**Approved.**
643.	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan	Zito-Forte 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)… …….500mg	Form-5 Dy.No 17717 dated 21-07-2020 Rs.20,000/- Dated 21-07-2020	2's, 3's, 4's, 6's, 10x6's 10x3's 10's, 12's; As per SRO	New License (inspection dated 19-02-2019 the panel unanimously recommends the grant of DML)	**Approved.**
644.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Zocin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Form-5 Dy.No 18315 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	6's, 10's; As per SRO	The firm was inspected on 07-11-2019 and conclusion of inspection was that the firm was operating at satisfactory level of cGMP compliant on the day of inspection	**Approved.**
645.	M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, S.I.T.E., Karachi, Pakistan	Kpazith 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 18322 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	1x6's; As per SRO	The firm was inspected on 16-10-2018 wherein the panel recommended the renewal of DML	**Approved.**
646.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Azogen 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… …500mg	Form-5 Dy.No 18696 dated 29-07-2020 Rs.20,000/- Dated 29-07-2020	6's; As per SRO	The firm was inspected on 12-12-2019 and the panel unanimously recommend	**Approved.**

						ed the grant of DML	
647.	M/s Standard Drug Company. Plot No 07-A, S.I.T.E Area, Karachi	Fluzicin 500mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 18765 dated 30-07-2020 Rs.20,000/- Dated 29-07-2020	As per SRO	Form 5 not submitted The reference formulation is film coated while you have applied for uncoated tablet. Revise the label claim, master formulation and manufacturing outline along with submission of applicable fee. Latest GMP inspection report	**Deferred for submission of Form 5, revision of formulation and manufacturing outline alongwith applicable fee.**
648.	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh	Azikar 500mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 18763 dated 30-07-2020 Rs.20,000/- Dated 29-07-2020	As per SRO	The firm was inspected on 07-02-2018 and Panel recommends the grant of DML. Revise the 1st page of form 5 as per prescribed format. The reference formulation is film coated while you have applied for uncoated tablet. Revise the label claim, master formulation	**Deferred for revision of formulation and manufacturing outline alongwith applicable fee.**

						and manufacturing outline along with submission of applicable fee.	
649.	**Deleted.**						
650.	M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road, Sargodha	Z-Max 500mg Tablet	Each film coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 18778 dated 30-07-2020 Rs.20,000/- Dated 30-07-2020	1x6's; As per SRO	The firm is granted GMP certificate based on inspection dated 28-01-2019.	**Approved.**
651.	M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I, Industrial Estate, Hattar	Azimal 500mg Tablet	Each film coated Tablet Contains: Azithromycin (as dihydrate)….500mg	Form-5 Dy.No 18775 dated 30-07-2020 Rs.20,000/- Dated 30-07-2020	6's; As per SRO	The firm was inspected on 13-02-2019 and 09-01-2020 and the panel unanimously recommends resumption of production activities in all sections of the firm.	**Approved.**
652.	M/s Harmann Pharmaceutical Laboratories Pvt Limited, 16-Km Multan Road, Lahore	Zithrobbas 500mg Tablet	Each film coated Tablet Contains: Azithromycin as dihydrate….500mg	Form 5 Dy.No. 9125 dated 28/04/2020 Rs. 20,000/- dated 28-04-2020	1x6's; As per SRO	Decision of 272st Meeting of CLB dated 13-11-2019**:** I- Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M/s Harmann Laboratories Lahore in as per recommendation of	**Approved.**

						panel inspection report dated 09-10-2019 in following sections. a- Sterile Section-I (General Injection) b- Sterile Section-III (Hormonal Injection) II- Regularize the layout plan of Hormonal Section, as per recommend ations of the panel in the reort dated 13-06-2019 & 08-10-2019.	
653.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar	Ezimark 500mg Tablet	Each Film coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Form 5 Dy.No. 15441 dated 30/06/2020 Rs. 20,000/- dated 30-06-2020	As per SRO	Last GMP inspection dated 04-09-2018 & 26-09-2018 and panel unanimousl y recommend s the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK. Undertakin g at the end of form 5 is missing	**Approved.**

2.Azithromycin Tablet 250mg:
Composition: Each Film coated tablet contains: Azithromycin as dihydrate…….250mg
Availability in RRAs: Azithromycin 250mg Film-Coated Tablets MHRA Approved
ME too status: Azithrolide 250mg tablet of M/s Heal Pharma (Reg. # 084233)
Specifications: USP

Sr.	Name of	Brand	Composition	Diary no. / Date /	Pack	Remarks/	Decision

No.	applicant	Name		fee / form	Size / Price	GMP status	
654.	M/s Ameer Pharma. 23 KM-Sheikhupura Road, Lahore	Azomeer 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Form-5 Dy.No 15118 dated 29-06-2020 Rs.20,000/- Dated 29-06-2020	3's, 6's, 7's, 10's, 14's, 20's, 28's, 30's; As per SRO	The firm was inspected on 9-12-2019 and 26-01-2020 and panel recommends renewal of DML	**Approved.**
655.	M/s Metro Pharmaceuticals. Plot # 14, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi	Otisthro 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 15805 dated 02-07-2020 Rs.20,000/- Dated 02-07-2020	2's, 4's, 6's, 10's, 12's; As per SRO	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.	**Approved.**
656.	M/s Linz Pharmaceuticals Pvt Ltd, Plot No 31-G & 31-H, Sector 15 Korangi Induatrial Area Karachi	Azax 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 16165 dated 07-07-2020 Rs.20,000/- Dated 06-07-2020	6's, 10's; As per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.	**Approved.**
657.	M/s Bosch Pharmaceuticals Pvt Ltd. Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Zezot 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 16170 dated 07-07-2020 Rs.20,000/- Dated 06-07-2020	6's, 10's; As per SRO	Inspection dated 17/09/2019, Acceptable level of GMP compliance.	**Approved.**
658.	M/s Munawar Pharma Pvt Ltd. 31 Km, Ferozepur Road, Lahore	M-Zith 250mg Tablet	Each film Coated Tablet Contains: Azithromycin as Dihydrate…….250mg	Form-5 Dy.No 13955 dated 17-06-2020 Rs.20,000/- Dated 17-06-2020	6' 10's; As per SRO	GMP certificate issued based on inspection dated 07-11-2017 The firm revised the label claim from uncoated to film coated tablets along with submission of Rs 5000/- on	**Approved.**

						deposit slip No.2026334 dated 31-08-2020	
659.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK	Azor 250mg film coated Tablet	Each film coated Tablet Contains: Azithromycin as dihydrate …250mg	Form-5 Dy.No 11427 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	1x10's As per SRO	The firm applied on prescribed form 5 for the product along with undertaking at the end of form 5. The firm revised the label claim from uncoated to film coated tablets without submission of applicable fee. Latest GMP inspection report not submitted Justification for addition of 2% overage	**Deferred for submissioin of justification for addition of 2% overage, GMP status, fee for revision of formulation**
660.	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad	Karzit 250mg tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate) …250mg	Form-5 Dy.No 17875 dated 22-07-2020 Rs.20,000/- Dated 22-07-2020	2's, 3's, 4's, 6's, 10x6's 10x3's 10's, 12's; As per SRO	Firm was inspected on 17-12-2019 and conclusion was: basic elements of GMP compliance reference to schedule B-II are in place and complied with.	**Approved.**
661.	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan	Zito 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)… 250mg	Form-5 Dy.No 17718 dated 21-07-2020 Rs.20,000/- Dated 21-07-2020	2's, 3's, 4's, 6's, 10x6's 10x3's 10's, 12's;	New License (inspection dated 19-02-2019 the panel unanimously recommend	**Approved.**

					As per SRO	s the grant of DML)	
662.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Zocin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Form-5 Dy.No 18340 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	6's, 10's; As per SRO	The firm was inspected on 07-11-2019 and conclusion of inspection was that the firm was operating at satisfactory level of cGMP compliant on the day of inspection	**Approved.**
663.	M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, S.I.T.E., Karachi, Pakistan	Kpazith 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 18321 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	1x6's; As per SRO	The firm was inspected on 16-10-2018 wherein the panel recommended the renewal of DML	**Approved.**
664.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Azogen 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Form-5 Dy.No 18688 dated 29-07-2020 Rs.20,000/- Dated 29-07-2020	6's; As per SRO	The firm was inspected on 12-12-2019 and the panel unanimously recommended the grant of DML	**Approved.**
665.	**Deleted.**						
666.	AAA Health Pharmaceuticals Laboratories. Plot# 9A, Street # N-5, National Industrial Zone, Rawat, Islamabad	Aizomax 250mg Tablet	Each Film Coated Tablet Contains: Aizthromycin as Dihydrate… …250mg	Form 5 Dy.No. 11684 dated 20/05/2020 Rs. 20,000/- dated 20-05-2020	3's, 6's; As per SRO	The firm was inspected on 09-10-2019 and conclusion of inspection was: The inspection concluded and firm request acceded to	**Approved.**

						complete the work and appoint technical staff as required under law along with instruments repair work. Form 5 has not been signed by signatory	
667.	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Winkthro 250mg Tablet	Each Film coated Tablet Contains: Azithromycin as Dihydrate……250mg	Form 5 Dy.No. 12599 dated 04/06/2020 Rs. 20,000/- dated 03-06-2020	As per SRO	Last GMP inspection conducted on 20-12-2017 and report concludes that the panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest.	**Approved.**

3.Azithromycin powder for oral suspension 200mg/5ml:
Composition:
Each 5ml reconstituted suspension Contains:
Azithromycin monohydrate eq to Azithromycin…200mg
Availability in RRAs: Azithromycin 200mg/5ml powder for oral suspension MHRA Approved.
Me-too status:
Palthro Dry Suspension 200mg/5ml by M/s Palpex Pharmaceuticals (Reg. No. 082947)
Specifications: USP

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
668.	M/s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi	Azicin Dry Powder Suspension 200mg/5ml	Each 5ml prepared suspension contains: 204.8mg Azithromycin monohydrate eq to 200mg azithromycin …200mg/5ml	Form-5 Dy.No 11412 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	60ml, 30ml; As per SRO	Last GKP inspection of the firm was conducted on 26-02-2019 and concluded satisfactory level of GMP compliance	**Deferred for updated GMP status**
669.	M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, S.I.T.E., Karachi, Pakistan	Kpazith 200mg/5ml Dry Powder Suspension	Each 5ml Contains: Azithromycin monohydrateEq. to Azithromycin …200mg	Form-5 Dy.No 18320 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	15ml; As per SRO	The firm was inspected on 16-10-2018 wherein the panel recommended the renewal of DML Firm submitted renewal inspection report showing dry powder suspension (cephalosporin) section and doesnot have dry powder suspension (general) section	**Deferred for confirmation of required manufacturing facility for applied formulation.**

4.Azithromycin for suspension 100mg/5ml:
Composition:
Each 5ml reconstituted suspension Contains:
Azithromycin as dihydrate……..…100mg
Availability in RRAs: ZITHROMAX (100mg/5ml) for oral suspension USFDA Approved.
Me-too status: Azitma 100mg/5ml dry suspension of M/s Sami Karachi. (Reg.# 074901)
Specifications: USP

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
670.	M/s Bosch Pharmaceuticals Pvt Ltd.	Zezot 100mg/5ml Suspension	Each 5ml Contains:	Form-5 Dy.No 16169 dated 07-07-2020	15ml, 30ml, 60ml;	Inspection dated 17/09/2019,	**Approved.**

	Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan		Azithromycin Dihydrate Eq. to Azithromycin …100mg	Rs.20,000/- Dated 06-07-2020	As per SRO	Acceptable level of GMP compliance.	
671.	M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, S.I.T.E., Karachi, Pakistan	Kpazith 100mg/5ml Dry Powder Suspension	Each 5ml Contains: Azithromycin dihydrate Eq. to Azithromycin …100mg	Form-5 Dy.No 18319 dated 27-07-2020 Rs.20,000/- Dated 27-07-2020	15ml; As per SRO	The firm was inspected on 16-10-2018 wherein the panel recommended the renewal of DML Firm submitted renewal inspection report showing dry powder suspension (cephalosporin) section and doesnot have dry powder suspension (general) section	**Deferred for confirmation of required manufacturing facility for applied formulation.**
672.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H, Sector 15 Korangi Induatrial Area Karachi ***Contract manufactured By:*** M/s Bosch Pharmaceuticals Pvt Ltd. Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Azax 100mg/5ml Suspension	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin …100mg	Form-5 Dy.No 16164 dated 07-07-2020 Rs.50,000/- Dated 06-07-2020	15ml, 30ml, 60ml; As per SRO	Inspection of Bosch Pharma dated 17/09/2019, Acceptable level of GMP compliance. The firm submitted contract manufacturing agreement between M/s Linz Pharmaceuticals and M/s Bosch Pharmaceuticals The firm submited list of 4	**Approved.**

						approved sections The firm did not submit list of products already registered/approved on contract manufacturing in the name of applicant The firm submitted list of 07 applied products for contract manufacturing.	

5.Azithromycin capsule 250mg:
Composition: Each Capsule Contains:
Azithromycin Dihydrate eq to Azithromycin……..……250mg
Availability in RRAs: Azithromycin 250mg capsules MHRA Approved
ME too status: Zidor Capsule 250mg of M/s Winthrox Karachi. (Reg.# 074943)
Specifications: USP
Note: Amperometer electrochemical with dual glassy carbon electrodes is required as per available monograph of USP 42.

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
673.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK	Cazithro 250mg Capsule	Each Capsule Contains: Azithromycin as dihydrate …250mg	Form-5 Dy.No 11430 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	6's; As per SRO	The firm applied on prescribed form 5 for the product alongwith undertaking at the end of form 5 Latest GMP inspection report is not submitted	**Deferred for updated GMP status of the firm by QA & LT.**
674.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Bio-Az 250mg Capsule	Each Hard Gelatin Capsule Contains: Azithromycin as	Form-5 Dy.No 18687 dated 29-07-2020 Rs.20,000/- Dated 29-07-2020	6's; As per SRO	The firm was inspected on 12-12-2019 and the panel unanimousl	**Deferred for completion of Form 5.**

			Dihydrate…250mg			y recommended the grant of DML Undertaking at the end of form5 submitted without signature	
675.	M/s Standard Drug Company. Plot No 07-A, S.I.T.E Area, Karachi	Fluzicin 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 18764 dated 30-07-2020 Rs.20,000/- Dated 29-07-2020	As per SRO	Revise the 1st page of form 5 as per prescribed format. Also form 5 submitted without signature of applicant Blistering and packing not mentioned in manufacturing outline. Submit complete manufacturing outline Latest GMP inspection report	**Deferred for correction of Form 5 and GMP status.**
676.	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh	Azikar 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 18762 dated 30-07-2020 Rs.20,000/- Dated 29-07-2020	As per SRO	The firm was inspected on 07-02-2018 and Panel recommends the grant of DML. Revise the 1st page of form 5 as per prescribed format. Blistering and packing not mentioned in manufacturing outline. Submit	**Deferred for correction of Form 5.**

						complete manufacturing outline	
677.	M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha	Z-Max 250mg Capsule	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Form-5 Dy.No 18780 dated 30-07-2020 Rs.20,000/- Dated 30-07-2020	1x6's, 10's; As per SRO	The firm is granted GMP certificate based on inspection dated 28-01-2019.	**Approved.**

6.Azithromycin capsule 500 mg:
Composition: Each Capsule Contains:
Azithromycin Dihydrate eq to Azithromycin……..……500mg
Availability in RRAs: Could not be confirmed
ME too status: Azithromycin 500mg Capsules by M/s Unipharma (Reg. No. 071422)
Specifications:
USP
Note: Amperometer electrochemical with dual glassy carbon electrodes is required as per available monograph of USP 42.

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
678.	M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I, Industrial Estate, Hattar	Azimal 500mg Capsule	Each capsule Contains: Azithromycin as dihydrate……..500mg	Form-5 Dy.No 18776 dated 30-07-2020 Rs.20,000/- Dated 30-07-2020	6's; As per SRO	The firm was inspected on 13-02-2019 and 09-01-2020 and the panel unanimously recommends resumption of production activities in all sections of the firm.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
679.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H, Sector 15 Korangi Induatrial Area Karachi	Azax 500mg capsule	Each capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 16166 dated 07-07-2020 Rs.20,000/- Dated 06-07-2020	3's, 6's, 10's; As per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in**

							275th meeting.
680.	M/s Bosch Pharmaceuticals Pvt Ltd. Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Zezot 500mg capsule	Each capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Form-5 Dy.No 16167 dated 07-07-2020 Rs.20,000/- Dated 06-07-2020	3's, 6's, 10's; As per SRO	Inspection dated 17/09/2019, Acceptable level of GMP compliance.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**

7.Azithromycin sachet 1000mg:
Composition: Each Sachet Contains:
Azithromycin as Dihydrate……...1g
Availability in RRAs: ZITHROMAX (1g) for oral suspension supplied in single-dose packets containing azithromycin as dihydrate USFDA Approved
ME too status: N/A
Specifications:
Innovators

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
681.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H, Sector 15 Korangi Industrial Area Karachi ***Contract manufactured By:*** M/s Bosch Pharmaceuticals Pvt Ltd. Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Azax 1gm Sachet	Each Sachet Contains: Azithromycin Dihydrate Eq. to Azithromycin …1000mg	Form-5D Dy.No 16163 dated 07-07-2020 Rs.50,000/- Dated 06-07-2020 **(contract + new molecule)?**	1x10's, 1x14's; As per SRO	Inspection of Bosch Pharma dated 17/09/2019, Acceptable level of GMP compliance. Submitted Fee is Rs. 50000/- (for contract manufacturing) and new molecule applied on contract manufacturing? The firm submitted contract manufacturing agreement between M/s Linz	**Deferred for confirmation of required manufacturing facility for applied formulation.**

						Pharmaceuticals and M/s Bosch Pharmaceuticals The firm submitted list of 4 approved sections The firm did not submit list of products already registered/approved on contract manufacturing in the name of applicant The firm submitted list of 07 applied products for contract manufacturing. Stability study data required	
682.	M/s Bosch Pharmaceuticals Pvt Ltd. Bosch House 221, 222, & 223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Zezot 1gm Sachet	Each Sachet Contains: Azithromycin Dihydrate Eq. to Azithromycin …1000mg	Form-5D Dy.No 16168 dated 07-07-2020 Rs.50,000/- Dated 06-07-2020	1x10's, 1x14's; As per SRO	Inspection dated 17/09/2019, Acceptable level of GMP compliance. Stability study data required	**Deferred for confirmation of required manufacturing facility for the applied formulation.**
683.	M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha	Z-Max 1g Sachet	Each sachet Contains: Azithromycin Dihydrate Eq. to Azithromycin …1g	Form-5 Dy.No 18779 dated 30-07-2020 Rs.50,000/- Dated 30-07-2020	1x10's, 1x3's; As per SRO	The firm is granted GMP certificate based on inspection dated 28-01-2019.	**Approved.**

8.Azithromycin lyophilized/ powder for solution for Infusion 500mg/vial:
Composition:
Each vial Contains:
Azithromycin dihydrate eq to Azithromycin…….500mg

Availability in RRAs:
ZITHROMAX (500mg) lyophilized powder for injection, for intravenous use USFDA Approved

Me-too status:
Macrocap 500mg Dry Powder Injection by M/s Aries Pharmaceuticals (Reg. No. 82589)
Specifications:
USP

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
684.	M/s BF Biosciences Limited. 5-Km, Sunder-Raiwind Road, Raiwind, Lahore, Pakistan	Azofer 500mg/Vial Lyophilized Powder for Solution for Infusion	Each Vial Contains: Azithromycin (as dihydrate)…500mg	Form-5 Dy.No 16818 dated 13-07-2020 Rs.20,000/- Dated 13-07-2020	10ml;As per SRO	Last GMP inspection conducted on 22-08-2019 wherein the panel recommended the renewal of DML	**Deferred for confirmation of manufacturing facility**

b. <u>Deferred cases (Human-Covid):</u>

685.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 5, M2-Pharmazone, 26 Km, Main Sharaqpur Road, Sheikhupura, Pakistan	Varibac 500mg IV lyophilized sterile powder for Injection	Each Vial Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11289 dated 18/05/2020 Rs. 20,000/- dated 18-05-2020 Form 5	1's vial, As per SRO	9,20-12-2019, The panel recommends grant of DML. General Dry powder Injection section (Pre-lyophilized) vial is present
	Previous Decision (295-DRB)	Deferred for confirmation of required manufacturing facility i.e., Lyophilized vial injectable section.				
	Evaluation by PEC	The firm has submitted letter No. F.1-1/2016-Lic dated 24th February 2020 issued by secretary CLB, in which General Dry powder Injection section (Pre-lyophilized) vial is granted while the applied product is lyophilized powder for Injection				
	Decision: Deferred for confirmation of required manufacturing facility i.e., Lyophilized vial injectable section.					

686.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan	Rocin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Form-5 Dy.No 16855 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	10's 14's 20's; As per SRO	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good. Master formulation and method of manufacturing not submitted
	Previous Decision (295-DRB)	Deferred for submission of master formulation and method of manufacturing.				
	Evaluation by PEC	The firm submitted master formulation and manufacturing method				
	Decision: Deferred for submission of fee applicable for variation in application.					

687.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan	Rocin 200mg/5ml Oral Powder Suspension	Each 5ml contains: Azithromycin monohydrate …200mg	Form-5 Dy.No 11425 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	30,60, 120ml ; As per SRO	2018- GMP compliance is rated as good.
	Previous Decision (295-DRB)	Deferred for correct salt form and fee				
	Evaluation by PEC	The firm submitted revised form 5 and revised label claim along with submission of Rs. 5000/- on deposite slip No. 1996272 dated 10-08-2020. The revised label claim is as under: Each 5ml contains: Azithromycin (as monohydrate)……200mg				
	Decision: Approved.					

Item No. I: Agenda of Evaluator PEC-IX

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

688.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 10/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…10mg Amlodipine as besylate…10mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved

		Atorvastatin (mg)			
		10	20	40	80
Amlodipine (mg)	2.5	X	X	X	--
	5	X	X	X	X
	10	X	X	X	X

	Me-too status	Corsafe AT 10/10 Tablets. Reg No. 68320
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
689.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 20/10 mg Tablet

	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…20mg Amlodipine as besylate…10mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved **Atorvastatin (mg)**: 10, 20, 40, 80 **Amlodipine (mg)**: 2.5 (X, X, X, --); 5 (X, X, X, X); 10 (X, X, X, X)
	Me-too status	Corsafe AT 10/20 Tablets. Reg No. 68321
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
690.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Lowvat-A 20/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…20mg Amlodipine as besylate…5mg
	Diary No. Date of R & I & fee	Dy. No. 13523; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CADUET® (amlodipine as besylate and atorvastatin as calcium) tablets, film-coated. USFDA approved **Atorvastatin (mg)**: 10, 20, 40, 80 **Amlodipine (mg)**: 2.5 (X, X, X, --); 5 (X, X, X, X); 10 (X, X, X, X)
	Me-too status	Zodip Plus 20 Tablet. Reg No. 83294
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
691.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex 0.025% Cream

	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide…0.25mg
	Diary No. Date of R & I & fee	Dy. No. 13562; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synlar Cream 0.025%. USFDA approved
	Me-too status	Dermolone Cream 0.025%. Reg. No. 41891
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
692.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Cream
	Composition	Each Gram of Cream Contains: Fluocinolone Acetonide…0.25mg Clioquinol…3mg
	Diary No. Date of R & I & fee	Dy. No. 13557; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Cream 0.025/3%. MHRA approved
	Me-too status	Synalar C Cream. Reg. No. 30866
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
693.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Fetrex C Ointment
	Composition	Each Gram of Ointment Contains: Fluocinolone Acetonide…0.25mg Clioquinol…3mg
	Diary No. Date of R & I & fee	Dy. No. 13556; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Clioquinol, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Synalar C Ointment 0.025/3%. MHRA approved
	Me-too status	Synalar C Ointment. Reg. No. 30865

	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
694.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Univate 0.05% Cream
	Composition	Each Gram of Cream Contains: Halobetasol Propionate…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13546; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10g, 15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravate® (halobetasol propionate) Cream, 0.05%. USFDA approved
	Me-too status	Halovate Cream 0.05%. Reg. No. 46990
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn..	
695.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Univate 0.05% Ointment
	Composition	Each Gram of Ointment Contains: Halobetasol Propionate…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13547; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10g, 15g, 30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravate® (halobetasol propionate) Ointment, 0.05%. USFDA approved
	Me-too status	Halovate Ointment 0.05%. Reg. No. 46989
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
696.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Laxolol Sachet
	Composition	Each Sachet Contains: Macrogol…13.125g

		Sodium Chloride…0.3507g Sodium Hydrogen Carbonate…0.1785g Potassium Chloride…0.0466g
	Diary No. Date of R & I & fee	Dy. No. 13574; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Osmotic laxative
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Movicol 13.8g sachet, powder for oral solution. Approved by MHRA
	Me-too status	Forlax Sachet. Reg. No. 82099
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
697.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Mebis Sachet
	Composition	Each Sachet Contains: Mebevirine as Hcl…135mg Ispaghula Husk…3.5mg
	Diary No. Date of R & I & fee	Dy. No. 13571; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Fybogel Mebeverine Granules for oral suspension Reckitt Benckiser Healthcare (UK) Limited, approved by MHRA, The firm has mentioned powder
	Me-too status	Mebsyl Sachet by Neutro Pharma (Pvt) Ltd., Lahore Reg. No. 74307
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	• Submit complete manufacturing outlines from dispensing to blistering
	Decision: Deferred for consideration on its turn.	
698.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Maltomax-F Syrup
	Composition	Each 5ml Contains: Iron (III) Hydroxide Polymaltose Eq. to Elemental Iron…50mg Folic Acid…0.35mg
	Diary No. Date of R & I & fee	Dy. No. 13552; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Iron in combination with folic acid
	Type of Form	Form 5

	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Poly-F Syrup. Reg. No. 64045
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
699.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Clospo 100mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Cyclosporine…100mg
	Diary No. Date of R & I & fee	Dy. No. 13566; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Immunosuppresants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NEORAL® Soft Gelatin 100mg Capsule. USFDA approved
	Me-too status	SANDIMMUN CAPSULES 100MG. Reg, No. 12176
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
700.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Clospo 50mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Cyclosporine…50mg
	Diary No. Date of R & I & fee	Dy. No. 13567; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Immunosuppresants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NEORAL® Soft Gelatin 50mg Capsule. USFDA not discontinued or withdrawn for safety or efficacy reasons
	Me-too status	CYSPINRAL CAPSULES 50MG. Reg, No. 18272
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	

701.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Nidin 10mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Nifedipine…10mg
	Diary No. Date of R & I & fee	Dy. No. 13569; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Nifedipine soft capsules 10 mg. MHRA approved
	Me-too status	Nifedil Sg Capsule 10mg. Reg. No. 31291
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
702.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Co-Ibtan 150/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…150mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13531; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Irbesartan and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Avalide tablet 150mg/12.5mg, film-coated. USFDA approved
	Me-too status	Co- Irbisaff Tablet 150/12.5. Reg. No. 77191
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
703.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Mefintin-EZ 80/480 mg Tablet
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R & I & fee	Dy. No. 13527; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Artemisinin and derivatives, combinations
	Type of Form	Form 5
	Finished product Specification	IP

	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation
	Me-too status	Eptrim-X 80/480mg Tablets. Reg. No. 75828
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
704.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	V Artan-S 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan…103mg
	Diary No. Date of R & I & fee	Dy. No. 13533; 07.03.2019 PKR. 20,000/-; 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO™ (sacubitril and valsartan) 97/103mg tablets, film-coated. USFDA approved (with box warning)
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 21.02.2019 with the following conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator(IX)	Submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A.
	Decision: Deferred for consideration on its turn.	
705.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Topride Tablets 50mg
	Composition	Each Film Coated Tablet Contains: Itopride Hcl…50mg
	Diary No. Date of R & I & fee	Dy. No. 9567; 01.03.2019 PKR. 20,000/-; 01.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Itopride hydrochloride tablet 50 mg. **PMDA** approved
	Me-too status	Itoride Tablet by Lexicon Pharmaceutical. Reg No. 42040
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	
	Decision: Approved with innovator' specifications.	

706.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Levozine Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Levocetirizine Dihydrochloride…5mg
	Diary No. Date of R & I & fee	Dy. No. 9565; 01.03.2019 PKR. 20,000/-; 01.03.2019
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities.	XYZAL levocetirizine hydrochloride 5 mg film coated tablet blister pack. TGA approved
	Me-too status	Norzin 5 mg Tablets, film-coated. Reg. No. 77965
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	
	Decision: Approved.	
707.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Skinvate Cream 0.1% w/w 5gm
	Composition	Each gram contains: Mometasone Furoate…1mg
	Diary No. Date of R & I & fee	Dy. No. 10483; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ELOCON® (mometasone furoate) Cream, 0.1% for topical use by Merck Sharp Dohme. **US-FDA** approved
	Me-too status	Hivate Creamby Saffron Pharma. Reg. No. 46432
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	
	Decision: Approved.	
708.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Fresh cream 0.1%
	Composition	Each gram contains: Adapalene…1mg
	Diary No. Date of R & I & fee	Dy. No. 10440; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Differin 0.1% Cream. **MHRA** approved
	Me-too status	Adapal Cream 0.1%. Reg. No. 83838
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	

709.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Rexin Tablets
	Composition	Each Tablet Contains: Piroxicam as betacyclodextrin …20mg
	Diary No. Date of R & I & fee	Dy. No. 9582; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CYCLADOL 20 mg scored tablet. **ANSM** approved
	Me-too status	Utrahit-beta Tablet. Reg. No. 81355
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
710.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Mevate Cream 0.05%
	Composition	Each gram contains: Fluticasone Propionate…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 10471; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluticasone propionate 0.05% cream. MHRA approved
	Me-too status	Fluticamax 0.05% Cream. Re. No. 83741
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	•
	Decision: Approved	
711.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Taco Ointment 0.03%
	Composition	Each gram contains: Tacrolimus…0.3mg
	Diary No. Date of R & I & fee	Dy. No. 10439; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Immunosuppressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	5g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ointment (0.01%, 0.03%) Ointment. USFDA approved
	Me-too status	Prolimus Ointment 0.03%. Reg. No. 73752
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specifications.	

712.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Velox Tablets 400mg
	Composition	Each film-coated tablet Contains: Moxifloxacin HCL eq to Moxifloxacin…400mg
	Diary No. Date of R & I & fee	Dy. No. 104557; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX (moxifloxacin as hydrochloride) 400mg tablets, film-coated. USFDA approved
	Me-too status	Moxizyan 400mg Tablets, film-coated. Reg. No. 77252
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	• The label claim was "each tablet contains", but the firm has mentioned coating composition and process. The firm revised the label claim to film-coated tablet.
	Decision: Deferred for submission of applicable fee for revision of label claim.	
713.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Meflam Tablets 50mg
	Composition	Each film-coated tablet contains: Diclofenac potassium…50mg
	Diary No. Date of R & I & fee	Dy. No. 10454; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac Potassium 50 mg Tablets, film-coated tablet. MHRA approved
	Me-too status	Diclobron-K 50mg Tablets. Reg. No. 54908
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	• The firm revised Diclofenac potassium…75mg to Diclofenac potassium…50mg without submission of any fee. • The label claim was "each tablet contains", but the firm has mentioned coating composition and process. The firm revised the label claim to film-coated tablet
	Decision: Deferred for submission of applicable fee for revision of strength.	
714.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Voral Tablets 100mg
	Composition	Each Film Coated SR Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R & I & fee	Dy. No. 10461; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP

	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Dicloflex Retard 100mg prolonged released tablet. MHRA Approved.
	Me-too status	Sintral SR Tablets 100mg. Reg. No. 81413
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	• The firm has applied for immediate release tablet. The firm revised the formulation (label claim, composition and manufacturing outlines) to Film Coated SR Tablet in line with the reference product without submission of fee.
	Decision: Deferred for submission of fee for revision of label claim.	
715.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Dexzole 60mg Capsule
	Composition	Each Capsule Contains: delayed release pellets Dexlansoprazole…60mg
	Diary No. Date of R & I & fee	Dy. No. 9582; 01.03.2019 PKR. 20,000/-; 01.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	DEXILANT (dexlansoprazole) delayed-release (30 and 60 mg) hyperomellose capsules, for oral use. USFDA approved
	Me-too status	New molecule
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	• The firm was asked to submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A. The firm submitted stability summary sheets of the pellets.
	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting Registration Board.	
716.	Name and address of manufacturer/ Applicant	M/s Masfa Industries Pvt Ltd 17th Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Dexzole 30mg Capsule
	Composition	Each Capsule Contains: delayed release pellets Dexlansoprazole…30mg
	Diary No. Date of R & I & fee	Dy. No. 9581; 01.03.2019 PKR. 20,000/-; 01.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	DEXILANT (dexlansoprazole) delayed-release (30 and 60 mg) hyperomellose capsules, for oral use. USFDA approved
	Me-too status	New molecule
	GMP status	The firm was inspected on 29.03.2019, good level of GMP compliance was reported
	Remarks of the Evaluator(IX)	• The firm was asked to submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A. The firm submitted stability summary sheets of the pellets.

	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting Registration Board.	
717.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Bromodys Tablets 2.5mg
	Composition	Each Tablet Contains: Bromocriptine as mesilate…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 10534; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Parlodel® SnapTabs® (bromocriptine mesylate) tablets, USP. USFDA approved
	Me-too status	Bromit Tablets 2.5mg. Reg. No. 68022
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Deferred for confirmation of required manufacturing facility for applied formulation.	
718.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Doxilin Syrup 100mg
	Composition	Each 5ml contains: Doxofylline…100mg
	Diary No. Date of R & I & fee	Dy. No. 10526; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	DOXOFILLINA ABC "200 mg/10 ml Sciroppo" Flacone da 200 ml. **AIFA** approved
	Me-too status	Unifyline Syrup. Reg. No. 47180
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the

		report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
719.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Donris Oral Solution 1mg/ml
	Composition	Each ml contains: Risperidone…1mg
	Diary No. Date of R & I & fee	Dy. No. 10528; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) oral solution. USFDA approved.
	Me-too status	Neoris 1mg/ml Solution. Reg. No. 82247
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
720.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dyprotone Tablets 50mg
	Composition	Each Tablet Contains: Cyproterone Acetate…50mg
	Diary No. Date of R & I & fee	Dy. No. 10535; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Antiandrogens, plain
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	50's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Androcur 50 mg tablets, uncoated. MHRA approved
	Me-too status	ANDROCUR TABLETS. Reg. No. 10221
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given

		in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Deferred for confirmation of required manufacturing facility for applied formulation.	
721.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dtsoviron Tablet 25mg
	Composition	Each Tablet Contains: Mesterolone…25mg
	Diary No. Date of R & I & fee	Dy. No. 10538; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	5-androstanon (3) derivatives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Pro-viron® 25mg tablet uncoated. MHRA approved
	Me-too status	Androviron 25mg Tablets. Reg. No. 030471
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk. • The firm submitted letter of approval of Tablet (Hormones) section.
	Decision: Deferred for confirmation of required manufacturing facility whether steroidal or non-steroidal hormone section for applied formulation.	
722.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dyz Tablets 0.02mg/3mg
	Composition	Each Film Coated Tablet Contains: Ethinylestradiol…0.02mg Drospirenone…3mg
	Diary No. Date of R & I & fee	Dy. No. 10536; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Progestogens and estrogens, fixed combinations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Eslarila 0.02 mg/3 mg film-coated tablets. MHRA approved
	Me-too status	YAZ TABLET 0.02/3mg film-coated. Reg. No. 59087
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations:

		Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Deferred for confirmation of required manufacturing facility whether steroidal or non-steroidal hormone section for applied formulation.	
723.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Lutison Vaginal Tablet 100
	Composition	Each Tablet Contains: Progesterone…100MG
	Diary No. Date of R & I & fee	Dy. No. 10531; 05.03.2019 PKR. 60,000/-; 05.03.2019
	Pharmacological Group	Pregnen (4) derivatives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lutigest 100 mg vaginal tablets. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A.
	Decision: Deferred for proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP or else submit stability study data as per requirements of 293rd meeting of Registration board.	
724.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Fenson Tablets 1mg
	Composition	Each Film Coated Tablet Contains: Finasteride……..…1mg
	Diary No. Date of R & I & fee	Dy. No. 10545; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Finasteride 1mg Film-coated Tablets. MHRA approved
	Me-too status	Prosin Tablet film-coated, 1mg. Reg. No. 83852
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Deferred for confirmation of required manufacturing facility whether steroidal or non-steroidal hormone section for applied formulation.	
725.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Fenson Tablets 5mg
	Composition	Each Film Coated Tablet Contains: Finasteride…5mg
	Diary No. Date of R & I & fee	Dy. No. 10537; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Finasteride 5 mg Tablets. MHRA approved
	Me-too status	Trichogen 5mg Tablet film-coated. Reg. No. 83722
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Deferred for confirmation of required manufacturing facility whether steroidal or non-steroidal hormone section for applied formulation.	
726.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dyferol Oral Drops
	Composition	Each ml contains: Cholecalciferol …14400 IU
	Diary No. Date of R & I & fee	Dy. No. 10523; 05.03.2019

		PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Vitamin D and analogues
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Sapvit-D3 14,400 IU/ml oral drops, solution. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A.
	Decision: Deferred for: • **Signature on Form 5.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
727.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Tramason 50mg capsule
	Composition	Each Capsule Contains: Tramadol Hcl…50mg
	Diary No. Date of R & I & fee	Dy. No. 10532; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Other opioids
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Tramadol Hydrochloride 50mg Capsules. MHRA approved
	Me-too status	TRAMAL CAPSULES 50mg. Reg. No. 10170
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•

	Decision: Approved	
728.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dymiga Tablet 50mg PR
	Composition	Each film coated prologed release tablet contains: Mirabegron…50mg
	Diary No. Date of R & I & fee	Dy. No. 10523; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	MYRBETRIQ® extended-release (film-coated) tablet, for oral administration contains either 25 mg or 50 mg. USFDA approved
	Me-too status	New molecule
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk. • Submit all the legal requirements meant for the product that requires the stability studies as per zone IV-A.
	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting.	
729.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dylovir Tablet 200mg
	Composition	Each Tablet Contains: Acyclovir…200mg
	Diary No. Date of R & I & fee	Dy. No. 10523; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Nucleosides and nucleotides excl. reverse transcriptase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	25's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Aciclovir 200mg tablets. MHRA approved
	Me-too status	SUPRAVIRAN TABLETS 200. Reg, No. 19539
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of

		GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
730.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dyfend Tablets 50mg
	Composition	Each Film Coated Tablet Contains: Voriconazole…50mg
	Diary No. Date of R & I & fee	Dy. No. 10529; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Triazole derivatives
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Voriconazole 50mg Film coated Tablet. MHRA approved
	Me-too status	Vorif tablets 50mg (Reg. # 069765)
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
731.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dyfend Tablets 200mg
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R & I & fee	Dy. No. 10527; 05.03.2019 PKR. 20,000/-; 05.03.2019
	Pharmacological Group	Triazole derivatives
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	VFEND® (voriconazole) 200mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Voric 200mg film-coated Tablet Reg No. 83272
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of

		GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
732.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dykote Oral Solution 500mg/5ml
	Composition	Each 5ml contains: Valproate Sodium…500mg
	Diary No. Date of R & I & fee	Dy. No. 10541; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Epilim Syrup by Aventis Pharma Limited. Approved by MHRA
	Me-too status	Velpril Liquid by Munawar Pharma, (Pvt) Ltd, Lahore. Reg. No. 27768
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk. • Provide proof of reference product (500mg/5ml) in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the strength (label claim and composition) to 200mg/5ml, along with submission of applicable fee. • Mention vehicle and its quantity in the master formula
	Decision: Deferred for: • **Signature on Form 5.** • **Revision of the strength (label claim and composition) in line with the reference product, along with submission of applicable fee.** • **Mentioning of vehicle and its quantity in the master formula**	
733.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dykote Tablets 500mg
	Composition	Each gastro resistant tablet contains: Valproate Sodium…500mg
	Diary No. Date of R & I & fee	Dy. No. 10540; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's; as per SRO

	Approval status of product in Reference Regulatory Authorities.	Belvo 500 mg gastro-resistant tablets. MHRA approved
	Me-too status	Wiproate 500mg Tablets. Reg. no. 64345 (does not depict enteric coating)
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Approved.	
734.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name + Dosage Form + Strength	Dykote Tablets 250mg
	Composition	Each gastro resistant tablet contains: Valproate Sodium…250mg
	Diary No. Date of R & I & fee	Dy. No. 10539; 05.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Belvo 250 mg gastro-resistant tablets. MHRA approved
	Me-too status	Wiproate 250mg Tablets. Reg. no. 64344 (does not depict enteric coating)
	GMP status	The firm was inspected on 11.01.2019 with the following recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator(IX)	• Form 5 has not been signed by Mr. Mehmood Ahmed Virk.
	Decision: Approved.	
735.	Name and address of manufacturer/ Applicant	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan
	Brand Name + Dosage Form + Strength	Unimotrigine 25mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…25mg
	Diary No. Date of R & I & fee	Dy. No. 3189; 23.01.2019 PKR. 20,000/-; 23.01.2019

	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 25 mg tablets. **MHRA** approved
	Me-too status	Sportin 25mg Tablets. Reg No. 70344
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019. The firm has been inspected again, wherein the panle recommended the resumption of production except sterile liquid infusion section. The date of inspection has not been mentioned.
	Remarks of the Evaluator(IX)	Submit complete manufacturing outlines from dispensing to blistering and packing.
	Decision: Deferred for submission of complete manufacturing outlines from dispensing to blistering and packing and confirming date of inspection.	
736.	Name and address of manufacturer/ Applicant	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan
	Brand Name + Dosage Form + Strength	Unimotrigine 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…50mg
	Diary No. Date of R & I & fee	Dy. No. 3188; 23.01.2019 PKR. 20,000/-; 23.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 50 mg tablets. **MHRA** approved
	Me-too status	Sportin 50mg Tablets. Reg No. 70345
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019. The firm has been inspected again, wherein the panle recommended the resumption of production except sterile liquid infusion section. The date of inspection has not been mentioned.
	Remarks of the Evaluator(IX)	Submit complete manufacturing outlines from dispensing to blistering and packing.
	Decision: Deferred for submission of complete manufacturing outlines from dispensing to blistering and packing and confirming date of inspection.	
737.	Name and address of manufacturer/ Applicant	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan
	Brand Name + Dosage Form + Strength	Unidonate 70mg Tablet
	Composition	Each Tablet Contains: Alendronic acid (as Sodium Trihydrate)…70mg
	Diary No. Date of R & I & fee	Dy. No. 3192; 23.01.2019 PKR. 20,000/-; 23.01.2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	FOSAMAX® (alendronate sodium Trihydrate eq. to 70mg free base) uncoated tablets, for oral use. **USFDA** approved

	Me-too status	Osoaid Tablets 70mg. Reg. No. 79761 (does not trihydrate form)
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019. The firm has been inspected again, wherein the panle recommended the resumption of production except sterile liquid infusion section. The date of inspection has not been mentioned.
	Remarks of the Evaluator(IX)	Submit complete manufacturing outlines from dispensing to blistering and packing. The firm revised sodium alendronate….70mg to Alendronic acid (as Sodium Trihydrate…70mg.
	Decision: Deferred for submission of complete manufacturing outlines from dispensing to blistering and packing and confirming date of inspection.	
738.	Name and address of manufacturer/ Applicant	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan
	Brand Name + Dosage Form + Strength	Unitroxib 60mg Tablet
	Composition	Each film-coated tablet Contains: Etoricoxib…60mg
	Diary No. Date of R & I & fee	Dy. No. 3190; 23.01.2019 PKR. 20,000/-; 23.01.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA etoricoxib 60mg film-coated tablet. **TGA** approved
	Me-too status	Gencox 60mg Tablets film-coated. Reg. No. 78839
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019. The firm has been inspected again, wherein the panle recommended the resumption of production except sterile liquid infusion section. The date of inspection has not been mentioned.
	Remarks of the Evaluator(IX)	• The firm revised the formulation to film-coated tablet in line with international reference product without submission of applicable fee. • Submit complete manufacturing outlines from dispensing to blistering and packing.
	Decision: Deferred for: • **Submission of fee for revision of formulation.** • **Submission of complete manufacturing outlines from dispensing to blistering and packing.** • **confirming date of inspection**	
739.	Name and address of manufacturer/ Applicant	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan
	Brand Name + Dosage Form + Strength	Prewit Injection IM and oral
	Composition	Each Injection Contains: Vitamin D3…500mcg
	Diary No. Date of R & I & fee	Dy. No. 3187; 23.01.2019 PKR. 20,000/-; 23.01.2019
	Pharmacological Group	Form 5
	Type of Form	BP
	Finished product Specification	As per DRAP Policy

	Pack size & Demanded Price	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule. VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule. **ANSM** approved
	Approval status of product in Reference Regulatory Authorities.	Accu-D Injection. Reg. No. 79755
	Me-too status	Form 5
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019. The firm has been inspected again, wherein the panle recommended the resumption of production except sterile liquid infusion section. The date of inspection has not been mentioned.
	Remarks of the Evaluator (IX)	Submit complete manufacturing outlines from dispensing to filling and packing.
	Decision: Deferred for submission of complete manufacturing outlines from dispensing to blistering and packing and confirming date of inspection	
740.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Glucotin 500/400 mg Tablet
	Composition	Each Film Coated Tablet Contains: Glucosamine Sulphate …500mg Chondroitin Sulphate…400mg
	Diary No. Date of R & I & fee	Dy. No. 8750; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Could not be confirmed**
	Me-too status	Dysflex Tablet (Glucosamine as Sulphate Sodium Chloride). Reg. No. 65964
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator(IX)	• The firm was asked to provide proof of reference product (same strength and formulation) in reference regulatory agencies as defined in 275th meeting of the registration Board. • The firm has applied for Glucosamine Sulphate as Sodium Chloride Salt…500mg. The firm was asked to justify in line with the reference product. The firm revised the label claim from: Glucosamine Sulphate as Sodium Chloride Salt…500mg Chondroitin Sulphate as Sodium Salt…400mg to: Glucosamine Sulphate…500mg Chondroitin Sulphate…400mg • This does not match with the reference product.
	Decision: Deferred for revision of formulation in line with reference product alonwith appliacable fee.	

741.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Avedopa 250/25 mg Tablet
	Composition	Each Film Coated Tablet Contains: Levodopa…250mg Carbidopa…25mg
	Diary No. Date of R & I & fee	Dy. No. 8747; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Co-Careldopa 25 mg/250 mg tablets. MHRA approved
	Me-too status	Validopa Tablets. Reg. No. 31109
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator[IX]	• Revise Carbidopa to Carbidopa as monohydrate in the label claim. • You have applied for film-coated tablet. Provide proof of reference product (same strength and formulation) in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the formulation to uncoated tablet along with submission of applicable fee.
	Decision: Deferred for: • **Revision of Carbidopa to Carbidopa as monohydrate in the label claim.** • **Revision of formulation in line with the reference product along with submission of applicable fee.**	
742.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Bupredol SR 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Bupropion HCl…150mg
	Diary No. Date of R & I & fee	Dy. No. 8744; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed USP specifications, wherein 25-45% drug release criterion has been mentioned in initial 1 h. moreover no gastric-resistant dissolution testing is present.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyban® 150 mg prolonged release tablets, film-coated. MHRA approved Zyban 150 mg prolonged release tablets, film-coated. HPRA approved
	Me-too status	Zylexx SR Tablets 150mg. Reg. No. 35470
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for

		early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator(IX)	• The firm revised bupropion to bupropion HCl in the label claim and master formula along WITHOUT submission of applicable fee. • The firm had applied for SR tablet. The firm revised the label claim from "Each Film Coated prolonged release tablet contains". • The firm has mentioned acrycoat in the core materials and has mentioned SR coating as a separate step but did not mention final coating in the manufacturing outlines. Upon clarification, the firm mentioned only one coating. • Bupropion HCl retard Teva 150 mg, modified-release tablets in Netherlands consists of pre-blending, wet granulation, drying, milling, blending final blending, compression, extended release coating, delayed release coating and packaging. However, in case of Bupropion HCl Sandoz retard 150 mg and 300 mg, modified-release tablets, the tablet cores are subsequently coated by the prolonged releasing ethyl cellulose coating, a gastro-resistant coating, and a hydrophilic film coating and finally imprinted. But Zyban 150 mg prolonged release tablets, film-coated, in HPRA does not depict delayed release coating.
	Decision: Deferred for: • **Fee for revision of salt form.** • **Clarification of formulation from the firm in line with the reference product.**	
743.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Rusidon 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Lurasidone Hcl…40mg
	Diary No. Date of R & I & fee	Dy. No.8743; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Indole derivatives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ARDIX LURASIDONE lurasidone hydrochloride 40 mg film-coated tablet blister pack. TGA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator(IX)	• Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies in zone IV-A.

	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting.	
744.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Rusidon 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Lurasidone Hcl…80mg
	Diary No. Date of R & I & fee	Dy. No.8742; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Indole derivatives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ARDIX LURASIDONE lurasidone hydrochloride 80 mg film-coated tablet blister pack. TGA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator(IX)	• Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies in zone IV-A.
	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting.	
745.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Fluzipine 6/25mg Capsule
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine…25mg
	Diary No. Date of R & I & fee	Dy. No. 10141; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Co-Depricap 6/25 Capsule by NabiQasim Karachi. Reg. No. 76135
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards.

		The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	The firm revised Fluoxetine…25mg to Fluoxetine as HCL…25mg without submission of applicable fee.
	Decision: Deferred for submission of applicable fee for revision of salt form.	
746.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Rapid 8mg Tablets
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 10152; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
747.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Rapid 8mg Injection
	Composition	Each 2ml contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 10153; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved
	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.

	Remarks of the Evaluator(IX)	• The firm has provided label claim is "Each 2ml contains" and provided manufacturing outlines of liquid injection. Revise the label claim and manufacturing outlines in line with the reference product along with submission of applicable fee.
	Decision: Deferred for confirmation of required manufacturing facitlity "Dry power injectable (Lyophilized)" for applied formulation and revision of the product in line with the reference product along with submission of applicable fee.	
748.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Leozo 600mg Tablets
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 10151; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	12's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. **USFDA approved**
	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection, M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
749.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Medonac 75mg/3ml Injection
	Composition	Each 3ml contains: Diclofenac Sodium…75mg
	Diary No. Date of R & I & fee	Dy. No. 10149; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac Sodium 75 mg/3 ml Solution for Injection
	Me-too status	Adfenac Injection 75mg/3ml/ Reg. No. 78635
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards.

		The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
750.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Thiomuslax 4mg
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R & I & fee	Dy. No. 10148; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg capsule. ANSM approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
751.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Periset 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCl dihydrate…8mg
	Diary No. Date of R & I & fee	Dy. No. 10155; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 8mg. Reg No. 82657
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	• The firm revised 'Ondansetron as Hydrochloride' to "Ondansetron as Hydrochloride dihydrate'. Revise the

		same in master formula and adjust its weight as per salt factor in master formula.
	Decision: Deferred for revision of Ondansetron Hydrochloride dihydrate in master formula and adjust its weight as per salt factor in master formula.	
752.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Periset 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCl dihydrate…4mg
	Diary No. Date of R & I & fee	Dy. No. 10154; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 4 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 4mg. Reg No. 82656
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	• The firm revised 'Ondansetron as Hydrochloride' to "Ondansetron as Hydrochloride dihydrate'. Revise the same in master formula and adjust its weight as per salt factor in master formula.
	Decision: Deferred for revision of Ondansetron Hydrochloride dihydrate in master formula and adjust its weight as per salt factor in master formula.	
753.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Furomide 20mg/2ml Injection
	Composition	Each 2ml contains: Furosemide…20mg
	Diary No. Date of R & I & fee	Dy. No. 10145; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	High-ceiling diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Furosemide Injection BP 20mg/2ml. MHRA approved
	Me-too status	Genmide 20mg/2ml Injection. Reg. No. 81546
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards.

		The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
754.	Name and address of manufacturer/ Applicant	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad
	Brand Name + Dosage Form + Strength	Tramol Plus Tablets 37.5mg/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl…37.5mg Paracetamol…325mg
	Diary No. Date of R & I & fee	Dy. No. 10144; 04.03.2019 PKR. 20,000/-; 04.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181
	GMP status	The firm was inspected on 30.01.2019 with the following recommendations: Keeping in view the above stated observations during inspection areas visited, the people met and the documents reviewed, and considering the findings of the inspection M/s Linear Pharma Rawat was considered to be operating at satisfactory level of compliance with GMP standards. The management is advised to rectify the observations and submit compliance as an earliest.
	Remarks of the Evaluator(IX)	• The firm had provided correct label claim. In the master formula, the firm revised Tramadol to Tramadol HCl.
	Decision: Approved	
755.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Acefen 150mg/3ml Injection
	Composition	Each 3ml contains: Aceclofenac…150mg
	Diary No. Date of R& I & fee	Dy.No 6221 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	5 x 3ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to

		overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
756.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Falcither 80mg/ml Injection
	Composition	Each ml contains: Artemether…80mg
	Diary No. Date of R& I & fee	Dy.No 8139 dated 25-02-2019 Rs.50,000/- Dated 22-02-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	1ml ampoule x 6's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation
	Me-too status	Artegen 80mg Injection by Fassgen Pharma (Reg# 056462)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.

	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
757.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Artimos Injection 30mg/vial
	Composition	Each vial contains: Artesunate…30mg
	Diary No. Date of R& I & fee	Dy.No 6222 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Artesunate dry powder vial 30mg. WHO approved
	Me-too status	Gen-M Injection 30mg. Reg. No. 76072
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of dry powder injection (lyophilized) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
758.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Artimos Injection 120mg/vial
	Composition	Each vial contains: Artesunate…120mg
	Diary No. Date of R& I & fee	Dy.No 6224 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Artesunate dry powder vial 120mg. WHO approved
	Me-too status	Gen-M Injection 120mg. Reg. No. 76073

	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of dry powder injection (lyophilized) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
759.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Artimos Injection 60mg/vial
	Composition	Each vial contains: Artesunate…60mg
	Diary No. Date of R& I & fee	Dy.No 6223 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Artesunate dry powder vial 60mg. WHO approved
	Me-too status	Artesunate Injection 60mg by Hilton Pharma (Reg# 015531)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of dry powder injection (lyophilized) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
760.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan

		Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Densee 5Mg/ml Injection
	Composition	Each ml contains: Cholecalciferol…5mg
	Diary No. Date of R& I & fee	Dy.No 6225 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Vitamin- D
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1ml ampoule x 5's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule & VITAMIN D3 GOOD 200,000 IU / 1 ml, oral solution in ampoule (ANSM France Approved)
	Me-too status	Drol- D injection by Regal Pharma (Reg. # 082005)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
761.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Deserve 40mg/2ml Injection
	Composition	Each 2ml contains Drotaverine hydrochloride…40mg
	Diary No. Date of R& I & fee	Dy.No 6226 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	2ml ampoule x 25's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 3 European Countries 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin

		Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
	Me-too status	NO-SPA Injection of Sanofi Aventis Pakistan
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
762.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Zumin 40mg Injection
	Composition	Each vial contains: Esomeprazole as sodium …40mg
	Diary No. Date of R& I & fee	Dy.No 6231 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for Injection vial. (TGA approved)
	Me-too status	Somezol Injection 40mg by Bosch (Reg# 045386)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of dry powder injection (lyophilized) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	

763.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Sucrose 100mg/5ml Injection
	Composition	Each 5ml contains: Iron sucrose…100mg
	Diary No. Date of R& I & fee	Dy.No 6229 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection (TGA Approved)
	Me-too status	Iroject Injection by Medley Pharma (Reg#070173)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section. • The reference product contains iron(III) hydroxide sucrose complex which is equivalent to 20mg/ml elemental Iron. Iron sucrose is gerneric term used for iron(III) hydroxide sucrose complex in TGA Australia.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
764.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Mecob 500mcg/ml Injection
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No 8138 dated 25-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Vitamin B-12
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	1ml ampoule x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Comezengen injection 500 µg of M/s Tatsumi Chemical (PMDA Japan Approved)

	Me-too status	Flench injection of Tabros Pharma (Reg. # 029050)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
765.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Noul 40mg Injection
	Composition	Each vial contains: Omeprazole as sodium…40mg
	Diary No. Date of R& I & fee	Dy.No 6227 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA Approved)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of dry powder injection (lyophilized) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
766.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan

		Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Pyrol 1000mg Injection
	Composition	Each 100ml vial contains: Paracetamol…1000mg
	Diary No. Date of R& I & fee	Dy.No 6228 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Anti pyretic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paracetamol 10 mg/ml Solution for Infusion (100ml vial contains 1000mg paracetamol) (MHRA Approved)
	Me-too status	Provas Infusion 10mg/ml by Sami Pharma (Reg# 053223)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance. Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
767.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan Contract manufactured by M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Tram 100mg/2ml Injection
	Composition	Each 2ml ampoule contains: Tramadol hydrochloride…100mg
	Diary No. Date of R& I & fee	Dy.No 6230 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Analgesics, Opiates
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tramadol 50mg/ml solution for injection of AS Kalceks (MHRA approved)
	Me-too status	Tamadol 100mg/2ml Injection of Highnoon (Reg#013194)
	GMP status	Semos Pharma: GMP inspection dated 04-07-2018 concluding good GMP compliance.

		Safe Pharma: The firm was inspected on 04.03.2019 with the following conclusion: All the above observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated GOOD.
	Remarks of the Evaluator(IX)	• The firm submitted that they have no product registered for contract manufacturing. • The firm submitted list of 08 approved sections. • Safe Pharmaceuticals has approval letter of liquid injection (general) section.
	Decision: Registration Board referred the case back to the panel to access overall capacity of the analytical equipments of firm including HPLC keeping in view pharmacopeial and other requirements of all registered drug products.	
768.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Aultaroxit CR 12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Paroxetine Hcl hemihydrate eq. to Paroxetine …12.5mg
	Diary No. Date of R & I & fee	Dy. No. 4664; 01.02.2019 PKR. 20,000/-; 01.02.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PAXILCR enteric, film-coated tablet 12.5mg. **USFDA** approved
	Me-too status	Jurox CR 12.5 Tablet. Reg. No. 81929 (**does not depict enteric, film coating and hemihydrate form**).
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator(IX)	• The firm revised label claim from "Paroxetine Hcl Eq. to" to "Paroxetine HCl hemihydrate eq. to". • Revise your label claim composition of excipients and manufacturing outline in line with the reference • Undertaking at the end of revised Form 5 has not been signed.
	Decision: Deferred for: • **Revision of label claim from "Paroxetine Hcl hemihydrate Eq. to" to "Paroxetine HCl hemihydrate eq. to paroxetine" and composition of excipients and manufacturing outline in line with the reference** • **Submission of undertaking at the end of revised Form 5.**	
769.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Arte Plus Tablet 80mg/480mg
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R & I & fee	Dy. No. 40355; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Drugs for urinary frequency and incontinence

	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 28's; Each tablet Rs. 60/-
	Approval status of product in Reference Regulatory Authorities.	WHO Approved formulation
	Me-too status	Eptrim-X 80/480mg Tablets. Reg. No. 75828
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• The firm revised the product from Film Coated Tablet to plain tablet without submission of applicable fee. • The cover letter was meant for 80/480mg strength. However, all other documents were meant for 20mg and rivaroxaban has been mentioned. The firm submitted enclosure of Form 5 with correct label claim and other contents without submission of applicable fee. • First page of Form 5 is still missing.
	Decision: Deferred for following: • **Submission of Form-5 alongwith fee for revision of formulation.** • **Updated GMP inspection report from QA & LT.**	
770.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Rivakem Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R & I & fee	Dy. No. 40385; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 28's; Rs. 7270/- per 14 tablets
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 15 mg film-coated tablets. MHRA approved
	Me-too status	Rivaxo 15mg film-coated Tablet. Reg. No. 80790
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	
	Decision: Deferred for submission of latest GMP inspection report.	
771.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemyfenac 100mg Tablet
	Composition	Each Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R & I & fee	Dy. No. 40382; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aceclofenac 100 mg film-coated Tablets. MHRA approved
	Me-too status	Anac 100mg Tablet. Reg. No. 81502
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	The firm has applied for plain tablet. Coating composition are mentioned thereof. However, the manufacturing outlines

		does not depict coating process. The firm revised the manufacturing outlines. Revision of label claim to film-coated tablet is required.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Revision of label claim to film-coated tablet along with submission of applicable fee.**	
772.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemsartan Tablet 5mg/160mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…5mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 40384; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Could not be confirmed
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160. USFDA approved
	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator[IX]	• The firm had applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula. • In master formula, the label claim is amlodipine as besilate. However, in Form 5 it is amlodipine. The firm did not clarify the same. • The firm shall submit properly filled enclosure of Form 5. • The firm shall also revise amlodipine as besilate to amlodipine besilate in master formula only.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of applicable fee for revision of label claim to film-coated tablet.** • **Revision of amlodipine to amlodipine as besilate in Form 5.** • **Submission of enclosure of Form 5.** • **Revision of amlodipine as besilate to amlodipine besilate in master formula only.** • **Pack size & Demanded Price**	
773.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemsartan Tablet 10mg/160mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…10mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 40383; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Could not be confirmed
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 10/160. USFDA approved
	Me-too status	VALTAN -M 170 PLUS TABLET. Reg. No. 77207

	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• The firm has applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula. • In master formula, the label claim is amlodipine as besilate. However, in Form 5 it is amlodipine. The firm did not clarify the same. • The firm shall submit properly filled enclosure of Form 5. • The firm shall also revise amlodipine as besilate to amlodipine besilate in master formula only.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of applicable fee for revision of label claim to film-coated tablet.** • **Revision of amlodipine to amlodipine as besilate in Form 5.** • **Submission of enclosure of Form 5.** • **Revision of amlodipine as besilate to amlodipine besilate in master formula only.** • **Pack size & Demanded Price**	
774.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kem- Mont 10mg Tablet
	Composition	Each chewable tablet Contains: Montelukast (as sodium)…….10mg
	Diary No. Date of R & I & fee	Dy. No. 40388; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s, 20’s, 14’s, 30’s, 40’s, 50’s,60’s, 70’s, 80’s, 90’s, 100; Rs. 100 per tablet
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required. • Provide proof of approval of me-too product (name registration number and name of company) by DRAP. • Revise “Montelukast sodium eq. to. Montelukast” to “Montelukast sodium” in master formula only.
	Decision: Deferred for: • **Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board.** • **Proof of approval of me-too product (name registration number and name of company) by DRAP.** • **Revision of Montelukast sodium eq. to. Montelukast” to “Montelukast sodium” in master formula only.**	
775.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kem- Mont 5mg Tablet

	Composition	Each chewable tablet Contains: Montelukast (as sodium)…….5mg
	Diary No. Date of R & I & fee	Dy. No. 40387; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 30's, 40's, 50's,60's, 70's, 80's, 90's, 100; Rs. 100 per tablet
	Approval status of product in Reference Regulatory Authorities.	SINGULAIR® (montelukast sodium) Chewable Tablets. USFDA approved
	Me-too status	Nohist Chewable Tablet 5mg. Reg. No. 85712
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	Revise "Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Revision of Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.**	
776.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemyflox 400mg Tablet
	Composition	Each Film-coated tablet Contains: Moxifloxacin HCl…400mg
	Diary No. Date of R & I & fee	Dy. No. 40380; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's; Rs. 465/-
	Approval status of product in Reference Regulatory Authorities.	AVELOX (moxifloxacin as hydrochloride) 400mg tablets, film-coated. USFDA approved
	Me-too status	Moxizyan 400mg Tablets, film-coated. Reg. No. 77252
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	Undertaking at the end of Form 5 is missing.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of undertaking at the end of Form 5.**	
777.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemylid 600mg Tablet
	Composition	Each film-coated tablet Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 40381; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	12's; Rs. 980/-
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) 600mg tablets (film-coated) for oral use by Pharmacia and Upjohn. US-FDA approved
	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	

	Decision: Deferred for submission of latest GMP inspection report.	
778.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemadol-P 37.5/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol hcl….37.5mg Paracetamol…325mg
	Diary No. Date of R & I & fee	Dy. No. 40379; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Rs. 190/-
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too status	Tril-P Tablet. Reg. No. 78181
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	First page of Form 5 is missing. Revise tramadol as HCl to tramadol HCl and mention correct quantity of tramadol HCl, i.e., 37.5mg in Master formula.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of Form 5 (first page).** • **Revision of tramadol as HCl to tramadol HCl (label claim and composition) and mentioning the correct quantity of tramadol HCl, i.e., 37.5mg in Master formula.**	
779.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemroxen-E Tablet 500/20mg
	Composition	Each Delayed Release Tablet Contains: Naproxen…500mg Esomeprazole…20mg
	Diary No. Date of R & I & fee	Dy. No. 40377; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specification
	Pack size & Demanded Price	??
	Approval status of product in Reference Regulatory Authorities.	VIMOVO (naproxen and esomeprazole magnesium trihydrate) delayed-release tablets, for oral use (375 mg enteric-coated naproxen /20 mg immediate-release esomeprazole film-coated or 500 mg enteric-coated naproxen /20 mg immediate-release esomeprazole film-coated). US-FDA approved
	Me-too status	Tril-P Tablet. Reg. No. 78181
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• First page of Form 5 is missing. • The manufacturing process starts with producing a core tablet with naproxen. This core tablet is manufactured by a conventional wet granulation process. The core tablet is coated with six layers of film-coating. An enteric coat and barrier coat are applied prior to the active coat. The fourth coat is the esomeprazole magnesium trihydrate coat. Revise

		the composition and manufacturing outlines accordingly. • Revise esomeprazole to esomeprazole as magnesium Trihydrate in the label claim along with submission of applicable fee, and adjust its weight in Master formula as per salt factor. • Clarification is required regarding the pack size and demanded price.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Clarification of formulation in line with the reference product.** • **Revision of esomeprazole to esomeprazole as magnesium Trihydrate in the label claim along with submission of applicable fee, and adjustment of its weight in Master formula as per salt factor.** • **Clarification regarding the pack size and demanded price.**	
780.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemfylin Syrup 100mg/5ml
	Composition	Each 5ml contains: Doxofylline…100mg
	Diary No. Date of R & I & fee	Dy. No. 40378; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	30ml; Rs. 170/-, 60ml; Rs. 180/-, 90ml; Rs. 170/-, 100ml; Rs. 220/-, 120ml; Rs. 350/-, 450ml; Rs. 500/-
	Approval status of product in Reference Regulatory Authorities.	DOXOFILLINA ABC "200 mg/10 ml Sciroppo" Flacone da 200 ml. AIFA approved
	Me-too status	Unifyline Syrup. Reg. No. 47180
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	First page of Form 5 is missing.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of Form 5 (first page).**	
781.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Zaridine Syrup 5mg/5ml
	Composition	Each 5ml contains: Loratadine …5mg
	Diary No. Date of R & I & fee	Dy. No. 40376; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml; Rs. 45/-
	Approval status of product in Reference Regulatory Authorities.	Loratadine 5 mg/ 5 ml syrup. MHRA approved
	Me-too status	Histagon Syrup 5mg/5ml. Reg. No. 28188
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	First page of Form 5 is missing.
	Decision: Deferred for: • **Submission of latest GMP inspection report.** • **Submission of Form 5 (first page).**	

782.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Triam 500mg Tablet
	Composition	Each film coated oral tablet contains: Tranexamic Acid…500mg
	Diary No. Date of R & I & fee	Dy. No. 9443; 01.03.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	2x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	CYKLOKAPRON tranexamic acid 500mg tablet, film-coated. TGA approved
	Me-too status	Traumax Tablet. Reg. No. 24787 (dose not depict film-coating)
	GMP status	The firm was inspected on 23.07.2018 with the following Recommendations/Desired Action: The firm was found in satisfactory compliance with GMP guidelines, documents including SOP's log books were found intact and implemented. Although the firm was directed to shift all of the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act, 1976/DRAP Act, 2012 and make available all the testing requisites including columns and certified reference standards.
	Remarks of the Evaluator(IX)	•
	Decision: Approved.	
783.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Nebid 10mg Tablet
	Composition	Each tablet contains: Nebivolol as HCl…10mg
	Diary No. Date of R & I & fee	Dy. No. 9445; 01.03.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1x14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 2.5mg, 5mg, 10mg, 20mg) tablets, uncoated. USFDA approved
	Me-too status	Bynevol 10mg Tablet by Atco Lab Karachi. Reg No. 81562
	GMP status	The firm was inspected on 23.07.2018 with the following Recommendations/Desired Action: The firm was found in satisfactory compliance with GMP guidelines, documents including SOP's log books were found intact and implemented. Although the firm was directed to shift all of the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act, 1976/DRAP Act, 2012 and make available all the testing requisites including columns and certified reference standards.

	Remarks of the Evaluator(IX)	• The firm revised the formulation (label claim, composition and manufacturing outlines) from fil-coated to uncoated tablet, along with submission of Rs. 5000/- fee.
	Decision: Approved with innovator's specification.	
784.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Nebid 5mg Tablet
	Composition	Each tablet contains: Nebivolol as HCl…5mg
	Diary No. Date of R & I & fee	Dy. No. 9444; 01.03.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1x14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 2.5mg, 5mg, 10mg, 20mg) tablets, uncoated. USFDA approved
	Me-too status	Bynevol 5mg Tablet by Atco Lab Karachi. Reg No. 81099
	GMP status	The firm was inspected on 23.07.2018 with the following Recommendations/Desired Action: The firm was found in satisfactory compliance with GMP guidelines, documents including SOP's log books were found intact and implemented. Although the firm was directed to shift all of the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act, 1976/DRAP Act, 2012 and make available all the testing requisites including columns and certified reference standards.
	Remarks of the Evaluator(IX)	• The firm revised the formulation (label claim, composition and manufacturing outlines) from fil-coated to uncoated tablet, along with submission of Rs. 5000/- fee.
	Decision: Approved with innovator's specification.	
785.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Olmedin 5/20mg Tablet
	Composition	Each film coated oral tablet contains: Amlodipine besylate eq to Amlodipine…5mg Olmesartan Medoxomil…20mg
	Diary No. Date of R & I & fee	Dy. No. 9448; 01.03.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	2x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	AZOR 5/20 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 5mg/20mg Tablet. Reg. No. 83256
	GMP status	The firm was inspected on 23.07.2018 with the following Recommendations/Desired Action: The firm was found in satisfactory compliance with GMP guidelines, documents including SOP's log books were found intact and implemented. Although the firm was

		directed to shift all of the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act, 1976/DRAP Act, 2012 and make available all the testing requisites including columns and certified reference standards.
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
786.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Olmedin 5/40mg Tablet
	Composition	Each film coated oral tablet contains: Amlodipine besylate eq to Amlodipine…5mg Olmesartan Medoxomil…40mg
	Diary No. Date of R & I & fee	Dy. No. 9447; 01.03.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	2x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	AZOR 5/40 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 5mg/20mg Tablet. Reg. No. 883257
	GMP status	The firm was inspected on 23.07.2018 with the following Recommendations/Desired Action: The firm was found in satisfactory compliance with GMP guidelines, documents including SOP's log books were found intact and implemented. Although the firm was directed to shift all of the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act, 1976/DRAP Act, 2012 and make available all the testing requisites including columns and certified reference standards.
	Remarks of the Evaluator(IX)	•
	Decision: Approved with innovator's specification.	
787.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Savix 100mg/5ml Dry Powder Suspension
	Composition	Each 5ml of reconstituted suspension contains: Cefixime Trihydrate eq to Cefixime…100mg
	Diary No. Date of R & I & fee	Dy. No. 6996; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Powder for 30ml suspension; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality

		assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
788.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Savix 200mg/5ml Dry Powder Suspension
	Composition	Each 5ml of reconstituted suspension contains: Cefixime Trihydrate eq to Cefixime…200mg
	Diary No. Date of R & I & fee	Dy. No. 6989; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Powder for 30ml suspension; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
789.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Savix 400mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate eq to Cefixime…400mg
	Diary No. Date of R & I & fee	Dy. No. 6990; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	5's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules, for oral use by Lupin Ltd for Lupin Pharma. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule by Nawan Lab. Karachi. Reg. No. 82219

	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
790.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	B-Cef IM Injection 250mg
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…250mg
	Diary No. Date of R & I & fee	Dy. No. 6993; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma)..
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
791.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	B-Cef IM Injection 500mg
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…500mg
	Diary No. Date of R & I & fee	Dy. No. 6986; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO

	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
792.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	B-Cef IV Injection 250mg
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…250mg
	Diary No. Date of R & I & fee	Dy. No. 6991; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
793.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	B-Cef IV Injection 500mg
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…500mg
	Diary No. Date of R & I & fee	Dy. No. 6994; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV by Wel Wink Pharmaceuticals. Reg. No. 78097
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma)..
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
794.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	B-Cef IV Injection 1g
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…1000mg
	Diary No. Date of R & I & fee	Dy. No. 7000; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 1 g (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection by Alkemy Pharma. Reg. No. 70663
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
795.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	C Pime 500mg dry powder Injection

	Composition	Each Vial Contains: Cefepime HCL with L arginine sterile eq to Cefepime…500mg
	Diary No. Date of R & I & fee	Dy. No. 6992; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Fourth generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use (500mg, 1g, 2g). USFDA Approved
	Me-too status	Cefevial Injection 500 mg IV Reg. No. 80029
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma). • The firm revised Cefepime HCL with L arginine sterile eq to Cefepime…500mg to Cefepime as HCl monohydrate with L-arginine. …500mg.
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
796.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	C Pime 1g dry powder Injection
	Composition	Each Vial Contains: Cefepime HCL with L arginine sterile eq to Cefepime…1g
	Diary No. Date of R & I & fee	Dy. No. 6988; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Fourth generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use (500mg, 1g, 2g). USFDA Approved
	Me-too status	Cefevial Injection 1g IV Reg. No. 80030
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and

		22 applied products for contact manufacturing of the applicant (M/sBriell Pharma). • The firm revised Cefepime HCL with L arginine sterile eq to Cefepime…1g to Cefepime as HCl monohydrate with L-arginine. …1g.
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
797.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	D-Rise 5mg/ml Injection IM/oral
	Composition	Each ml contains: Cholecalciferol …5mg
	Diary No. Date of R & I & fee	Dy. No. 6996; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Vitamin D and analogues
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule. VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule. **ANSM** approved
	Me-too status	Accu-D Injection. Reg. No. 79755
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
798.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Irolic 100mg/5ml Injection
	Composition	Each 5ml contains: Iron sucrose eq to elemental iron…100mg
	Diary No. Date of R & I & fee	Dy. No. 6997; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml ampule; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality

		assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma). • The reference product contains iron(III) hydroxide sucrose complex which is equivalent to 20mg/ml elemental Iron. Iron sucrose is gerneric term used for iron(III) hydroxide sucrose complex in TGA Australia.
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
799.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Linstar 600mg/300ml Injection
	Composition	Each 300ml vial contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 7006; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	300ml vial; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
800.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tolac 30mg/ml Injection
	Composition	Each ml contains: Ketorolac Trometamol…30mg
	Diary No. Date of R & I & fee	Dy. No. 6995; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml x 5's ampule; As per SRO

	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 30mg/1mL injection ampoule. TGA approved
	Me-too status	Syntor 30 mg Injection IV/IM. Reg. No.83365
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
801.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ondex 8mg/4ml Injection
	Composition	Each 4ml contains: Ondansetron as Hcl dihydrate…8mg
	Diary No. Date of R & I & fee	Dy. No. 6998; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	4ml ampule; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2mg/ml Solution for Injection or Infusion (1ml, 2ml, 4ml ampule). MHRA approved.
	Me-too status	Ondenles 8mg Injection (4ml). Reg. No. 80548 Adosetron 4mg Injection (2ml). Reg. No. 78789
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma). • The firm revised Ondansetron Hcl dihydrate…8mg to Ondansetron as Hcl dihydrate…8mg.
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
802.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Magnix 1g Injection
	Composition	Each Vial Contains: Cefoperazone sodium eq to Cefoperazone…500mg Sulbactum sodium eq to sulbactum…500mg

	Diary No. Date of R & I & fee	Dy. No. 7002; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
803.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Magnix 2g Injection
	Composition	Each Vial Contains: Cefoperazone sodium eq to Cefoperazone…1g Sulbactum sodium eq to sulbactum…1g
	Diary No. Date of R & I & fee	Dy. No. 7001 ; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
804.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave

		Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zymox 400mg/250ml Infusion
	Composition	Each ml contains: Moxifloxacin as HCl…1.6mg
	Diary No. Date of R & I & fee	Dy. No. 7001 ; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	250ml ampule; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and 22 applied products for contact manufacturing of the applicant (M/sBriell Pharma). • The firm revised Moxifloxacin HCl to Moxifloxacin as HCl in the label claim.
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
805.	Name and address of manufacturer/ Applicant	M/s Briell Pharmaceuticals Pvt Ltd. 538-C Sundar Industrial Estate Road, Lahore. By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nervex 500mcg/ml Injection
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R & I & fee	Dy. No. 7001 ; 19.02.2019 PKR. 50,000/-; 19.02.2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1mlx10's (ampule); As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mecobalamin injection 500μg (1ml). PMDA approved
	Me-too status	Balco 500mcg IM/IV Injection (1ml). Reg. No. 81484
	GMP status	Applicant: The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC System, quality control, quality assurance and production operations. The Briell Pharma found to be operating at satisfactory level of GMP compliance. Manufacturer: GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator(IX)	• The firm submitted 05 approved sections, no approved products for contract manufacturing and

		22 applied products for contact manufacturing of the applicant (M/sBriell Pharma).
	Decision: Deferred for capacity assessment of M/s Medisave pharmaceuticals, Lahore.	
806.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Irosid Injection (5ml)
	Composition	Each ml contains: Iron (III) Isomaltoside eq. to elemental Iron…100mg
	Diary No. Date of R & I & fee	Dy. No. 14946; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Iron, parenteral preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	5's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Monofer 100 mg/ml solution for injection/infusion (1ml, 2ml, 3ml, 5ml, 10ml ampule/vial) . **MHRA** approved
	Me-too status	Wisofer Injection. Reg. No. 78521
	GMP status	
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
807.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fonic Injection
	Composition	Each 2ml contains: Folinic acid (as calcium folinate)…15mg
	Diary No. Date of R & I & fee	Dy. No. 14949; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Folic acid analogs (not in ATC)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Calcium Folinate (eq to folinic acid) 7.5 mg/mL Injection (15mg/2ml). MHRA approved
	Me-too status	
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
808.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ronium Injection 50mg/5ml
	Composition	Each 5ml contains: Rocuronium Bromide…50mg
	Diary No. Date of R & I & fee	Dy. No. 14947; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Other quaternary ammonium compounds
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocuronium bromide 10 mg/ml solution for injection/infusion (**vial**). MHRA approved
	Me-too status	ESMERON INJECTION 50MG/5ML. Reg. No. 21154
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019

	Remarks of the Evaluator(IX)	• The firm has claimed ampule packing
	Decision: Deferred for consideration on its turn.	
809.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Saprin tablet
	Composition	Each film coated tablet contain: Amlodipine as besilate…5mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 14953; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160. USFDA approved
	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator(IX)	•
	Decision: Deferred for consideration on its turn.	
810.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Flunide Lotion 0.01% w/v
	Composition	Each ml of Lotion contains: Fluocinolone Acetonide…0.1%W/v
	Diary No. Date of R & I & fee	Dy. No. 14948; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications (available in USP as topical solution)
	Pack size & Demanded Price	60ml, 120ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator(IX)	• You have applied for lotion, but the composition in master formula are API in oily base. Justify • The firm submitted Derma-Smoothe/FS® fluocinolone acetonide Topical Oil, 0.01% approved in USFDA as reference product.
	Decision: Deferred for consideration on its turn.	
811.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mebewin MR Capsule
	Composition	Each extended release capsule contains: Mebeverine HCl (pellets)…200mg
	Diary No. Date of R & I & fee	Dy. No. 14950; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5

	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator(IX)	• The firm revised Mebeverine as HCl to Mebeverine HCl in the dossier. • The source of pellets is Vision Pharmaceuticals, Islamabad.
	Decision: Deferred for consideration on its turn.	
812.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Hepa-Zerm Sachet
	Composition	Each Sachet contains: L-Ornithine-L-Asperate…3g
	Diary No. Date of R & I & fee	Dy. No. 14954; 07.03.2019 PKR. 20,000/-; 07.03.2019
	Pharmacological Group	Liver therapy mentioned as ornithine oxoglurate salt
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	5's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Hepa-Merz Sachet containing ornithine aspartate (granules for solution). **AGES** approved
	Me-too status	Lolar Sachet. Reg. No. 76499
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 19.01.2019
	Remarks of the Evaluator(IX)	• The firm applied for powder for solution. The reference product is granules for solution. The firm revised the manufacturing outlines to granules.
	Decision: Deferred for consideration on its turn.	
813.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Cefo-B/Hilsum Injection 1gm
	Composition	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Diary No. Date of R & I & fee	Dy. No. 1219; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals

		Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• The firm revised the label claim from "Cefoperazone Sodium+ Sulbactam Sodium…1gm" to "Cefoperazone as Sodium…500mg and Sulbactam as Sodium…500mg. • Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
814.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Cefo-B/Hilsum Injection 2gm
	Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Diary No. Date of R & I & fee	Dy. No. 1220; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• The firm revised the label claim from "Cefoperazone Sodium+ Sulbactam Sodium…2gm" to "Cefoperazone as Sodium…1g and Sulbactam as Sodium…1g. • Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
815.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Heliphen/Helixone Injection 250mg IM
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…250mg
	Diary No. Date of R & I & fee	Dy. No. 1223; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO

	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
816.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Heliphen/Helixone Injection 500mg IM
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg
	Diary No. Date of R & I & fee	Dy. No. 1224; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
817.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Heliphen/Helixone Injection 1gmIM
	Composition	Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…1g
	Diary No. Date of R & I & fee	Dy. No. 1225; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 1g Powder for Solution for Injection. MHRA approved
	Me-too status	Esticef 1g Powder for Injection IM. Reg. No. 85082
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people

		met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
818.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Hiloran/Hiltax Injection 250mg
	Composition	Each Vial Contains: Cefotaxime sodium…250mg
	Diary No. Date of R & I & fee	Dy. No. 1226; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019 PKR
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be verified
	Me-too status	Varxiame 250mg IM/IV Injection. Reg. No. 49270
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
819.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Hiloran/Hiltax Injection 500mg
	Composition	Each Vial Contains: Cefotaxime sodium …500mg
	Diary No. Date of R & I & fee	Dy. No. 1227; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIME HEXAL INJECTION cefotaxime 500mg (as sodium) powder for injection. TGA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV by Wel Wink Pharmaceuticals. Reg. No. 78097
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	

820.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Hiloran/Hiltax Injection 1gm
	Composition	Each Vial Contains: Cefotaxime sodium…1gm
	Diary No. Date of R & I & fee	Dy. No. 1228; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIME INJECTION cefotaxime 1g (as sodium) powder for injection IV. TGA approved
	Me-too status	Cefotaxime 1g Injection. Reg. No. 49272
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
821.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lidocaine Injection 1% 20mg/2ml (ampule)
	Composition	Each 2ml contains: Lidocaine HCl…20mg
	Diary No. Date of R & I & fee	Dy. No. 1218; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Local anesthetics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	LIDOCAINE ACCORD 1% lidocaine (lignocaine) hydrochloride 20 mg/2 mL injection ampoule. TGA approved
	Me-too status	Lignosyn 1.0% injection IM. Reg. No. 83366
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
822.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi

	Brand Name + Dosage Form + Strength	Sterile water for injection 5ml
	Composition	Each ampoule contains: Sterile water for injection…5ml
	Diary No. Date of R & I & fee	Dy. No. 1221; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Sterile water for injection (1ml, 2ml, 3.2ml, 5ml and 10ml) ampule Glass class I. MHRA approved
	Me-too status	Sterile Water for injection 5ml . Reg. No. 81541
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
823.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan; contract manufacturing by: Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Sterile water for injection 10ml
	Composition	Each ampoule contains: Sterile water for injection…10ml
	Diary No. Date of R & I & fee	Dy. No. 1212; 10.01.2019 PKR. 20,000/-; 09.01.2019; PKR. 30,000/-; 15.03.2019
	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	STERILE WATER FOR INJECTION 100% (10ml) in vial. **USFDA** approved
	Me-too status	Water for Injection (sterile) 10ml in ampule. Reg. No. 76972
	GMP status	The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."
	Remarks of the Evaluator(IX)	• Form 5 signed by Regulatory affair manger.
	Decision: Approved.	
824.	Name and address of manufacturer/ Applicant	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Spasnil 80/80 mg Tablet
	Composition	Each Sugar Coated Tablet Contains: Phloroglucinol Dihydrate Eq. to Phloroglucinol…80mg Trimethyl Phloroglucinol…80mg
	Diary No. Date of R & I & fee	Dy. No.39547; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5

	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHLOROGLUCINOL / TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	The firm submitted GMP inspection report dated 15.03.2019, which conclude that the firm had maintained conformance to GMP compliance.
	Remarks of the Evaluator(IX)	• The firm was asked to submit updated (26 points), duly filled and signed Form 5. The firm submitted 34 points Form 5
	Decision: Approved with innovator's specifications.	
825.	Name and address of manufacturer/ Applicant	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Spasnil 40/0.04 mg Injection
	Composition	Each 4ml Ampoule Contains: Hydrated Phloroglucinol…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R & I & fee	Dy. No.39546; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SPASFON, solution injectable en ampoule (4ml). ANSM approved
	Me-too status	Spadix Injection. Reg. No. 29528
	GMP status	The firm submitted GMP inspection report dated 15.03.2019, which conclude that the firm had maintained conformance to GMP compliance.
	Remarks of the Evaluator(IX)	• The firm was asked to submit updated (26 points), duly filled and signed Form 5. The firm submitted 34 points Form 5.
	Decision: Approved with innovator's specifications.	
826.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Cekosil Cream 1%
	Composition	Each gram of cream contains; Terbinafine hydrochloride…10mg
	Diary No. Date of R& I & fee	Dy. No. 40314:: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack size & Demanded Price	10g: As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL 1% w/w Cream. USFDA Approved
	Me-too status	Terbiderm Cream 1% (Reg#032004)
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	

827.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Cekosil Gel 1% (w/w)
	Composition	Each gram contains: Terbinafine hydrochloride…1.0%
	Diary No. Date of R& I & fee	Dy. No. 40315: 05.12.2018 Rs.20,000/-:: 04.12.2018
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	10g, : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil AT 1% Gel. MHRA approved
	Me-too status	Cutis Gel 1%. Reg. No. 58518
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
828.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Perme-Lice Cream 5%
	Composition	Each gram contains: Permethrin …….50mg
	Diary No. Date of R& I & fee	Dy. No. 40310: 05.12.2018 Rs.20,000/- : 04.12.2018
	Pharmacological Group	Pyrethrines, incl. synthetic compounds
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications.
	Pack size & Demanded Price	30g ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Permethrin 5% w/w Cream. MHRA Approved
	Me-too status	Bioscab Cream (Reg#.074773)
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
829.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Perme-Lice Lotion 5% w/v
	Composition	Each ml contains: Permethrin ……5%
	Diary No. Date of R& I & fee	Dy.No. 40311: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Pyrethrines, incl. synthetic compounds
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications.
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Permilot Lotion 5% (w/v). Reg # 076033
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.

		Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required.
	Decision: Approved.	
830.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Flucon capsule 150mg
	Composition	Each capsule contains: Fluconazole……150mg
	Diary No. Date of R& I & fee	Dy. No. 40307: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Triazole derivatives
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	1's & 1x4's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluconazole 150mg Capsules. MHRA approved
	Me-too status	Conza Capsule. Reg. No. 84049
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
831.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Eflo Cream
	Composition	Each gram of tube contains: Eflornithine as HCl Monohydrate...139 mg (13.9%)
	Diary No. Date of R& I & fee	Dy.No Rs. 20,000: 04.12.2018
	Pharmacological Group	Other agents against leishmaniasis and trypanosomiasis
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1's (15g); As per SRO
	Approval status of product in Reference Regulatory Authorities.	VANIQA eflornithine hydrochloride 139mg/g cream tube. USFDA approved
	Me-too status	Depilus Cream 13.9% Reg. # 073869 (does not depict hydrate form).
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
832.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Isot Gel 0.05% w/w
	Composition	Each gram contains: Isotretinoin…0.5mg
	Diary No. Date of R& I & fee	Dy.No 40308: 05.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Isotrex gel 0.05% w/w. MHRA Approved
	Me-too status	Iso-Scot Gel 0.05%. Reg # 37706
	GP status	

		Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
833.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Ckolynz Tablet 400mg
	Composition	Each film-coated tablet contains: Linezolid …….. …..400mg
	Diary No. Date of R& I & fee	Dy.No 40316: 05.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification.
	Pack size & Demanded Price	1x 10's, 2x6's, 3x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use. not discontinued or withdrawn by US-FDA for safety or efficacy reasons
	Me-too status	Enliv 400mg Tablet. Reg No. 58096 (does not depict coating)
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX)	Name of signatory is missing on Form 5.
	Decision: Approved.	
834.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Ckolynz Tablet 600mg
	Composition	Each film-coated tablet contains: Linezolid …….. …..600mg
	Diary No. Date of R& I & fee	Dy.No 40317: 05.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification.
	Pack size & Demanded Price	1x 10's, 2x6's, 3x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX® (linezolid) tablets (film-coated) for oral use. not discontinued or withdrawn by US-FDA for safety or efficacy reasons
	Me-too status	Linstar 600mg Tablet. Reg No. 82689
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
835.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Genta-Bet Cream
	Composition	Each gram contains Betmethasone as dipropionate…..0.05% w/w. Gentamycin as sulphate……..0.1% w/w
	Diary No. Date of R& I & fee	Dy. No. 40312: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Aminoglycosides and glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification.
	Pack size & Demanded Price	15g: As per SRO

	Approval status of product in Reference Regulatory Authorities.	Diprogenta Cream. Approved in Germany ASK no. | Substance name | Amount of substance Gentamicin sulfate | 1.67mg Betamethasone Dipropionate (Ph.Eur.) | 0.64mg
	Me-too status	Effigenta Cream. Reg. No. 024375
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5
	Decision: Approved.	
836.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Genta-Bet Ointment
	Composition	Each gram contains Betmethasone as Dipropionate…..0.05% w/w Gentamycin as Sulphate…….0.1% w/w
	Diary No. Date of R& I & fee	Dy. No 40313: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Aminoglycosides and glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	15g: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diprogenta ointment. Approved in Germany ASK no. | Substance name | Amount of substance Gentamicin sulfate | 1.67mg Betamethasone Dipropionate (Ph.Eur.) | 0.64mg
	Me-too status	Effigenta Ointment. Reg. No. 024376
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
837.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Rivax 10mg Tablet
	Composition	Each film-coated tablet contains: Rivaroxaban……...10mg
	Diary No. Date of R& I & fee	Dy.No. 40322: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1x5's, 1x10's, 1x14's, 1x20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 10 mg film-coated. MHRA approved
	Me-too status	Xaroban 10mg Tablet. Reg. No. 76284
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
838.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Rivax 15mg Tablet
	Composition	Each film-coated tablet contains: Rivaroxaban……...15mg
	Diary No. Date of R& I & fee	Dy. No. 40323: 05.12.2018. Rs. 20,000: 04.12.2018

	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1x5's, 1x10's, 1x14's, 1x20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 15 mg film-coated tablets. MHRA approved
	Me-too status	Rivaxo 15mg film-coated Tablet. Reg. No. 80790
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
839.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Rivax 20mg Tablet
	Composition	Each film-coated tablet contains: Rivaroxaban…….... 20mg
	Diary No. Date of R& I & fee	Dy. No. 40324: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1x10's, 1x20's, 1x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xarelto 20mg Tablet of (USFDA approved)
	Me-too status	Xerelto 20mg Tablet by Bayer Pakistan (Reg. No. 072550)
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
840.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Ivab 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Ivabradine as hydrochloride …5mg
	Diary No. Date of R& I & fee	Dy. No. 40318: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1x4's, 4x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CORLANOR film-coated tablets, for oral use. USFDA approved
	Me-too status	Ivatab 5mg Tablet. Reg. No. 76154
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
841.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Ivab 7.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Ivabradine as hydrochloride …7.5mg
	Diary No. Date of R& I & fee	Dy. No. 40319: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Other cardiac preparations

	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1x4's, 4x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CORLANOR film-coated tablets, for oral use. USFDA approved
	Me-too status	Ivatab 7.5mg Tablet. Reg. No. 76155
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	Name of signatory is missing on Form 5.
	Decision: Approved.	
842.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Loxicam 4mg tablet
	Composition	Each film coated tablet contains Lornoxicam….. 4 mg
	Diary No. Date of R& I & fee	Dy. No. 40320: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 4 mg Filmtabletten (Swiss Medic approved)
	Me-too status	Noxilor Tablet. Reg. No. 84039
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	
	Decision: Approved.	
843.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd Plot # 50/28 Korangi Industrial Area Karachi
	Brand Name +Dosage Form + Strength	Loxicam 8mg tablet
	Composition	Each film coated tablet contains Lornoxicam….. 8mg
	Diary No. Date of R& I & fee	Dy. No. 40321: 05.12.2018. Rs. 20,000: 04.12.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	5's, 10's & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GP status	Last GMP inspection of M/s. CKD Pharmaceuticals was conducted on 04-09-2018, where in the compliance level of the firm was rated Good.
	Remarks of the Evaluator(IX).	
	Decision: Approved.	

b. Deferred cases

844.	**Name and address of manufacturer / Applicant**	**M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Ftaft EC 500mg Tablet

	Composition	Each enteric coated tablet contains: Naproxen…500mg
	Diary No. Date of R& I & fee	Dy No. 22942: 03.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Propionic acid derivatives.
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Naproxen 500 mg Gastro-resistant Tablets. **MHRA** approved
	Me-too status	Naps 500mg Tablet. Reg. No. 83344
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator (IX).	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. Name of signatory is missing at first place in Form 5; mentioned along with signature • The firm mentioned term EC in the brand name and applied for enteric coated tablet. Upon clarification, the firm submitted label claim as "Each enteric coated tablet contains". However, no coating compostion and coating process has been submitted.
	Previous decision	The Board in its 291st meeting deferred the case for submission of correct master formula and manufacturing outlines.
	Evaluation by PEC	The firm submitted revised Master formula and manufacturing outlines. Form 5 has been signed by manager regulatory affairs.
	Decision: Approved.	
845.	**Name and address of manufacturer / Applicant**	**Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Masaco Tablet 800mg
	Composition	Each dealyed release tablet contains: Mesalazine…….800mg
	Diary No. Date of R& I & fee	Dy No. 6962: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ASACOL® HD (mesalamine) delayed-release tablets, for oral use. **MHRA** approved Octasa 800 mg Modified Release Tablets. MHRA approved
	Me-too status	Pressurex 20mg film-coated Tablets. Reg. No. 67535
	GMP status	The firm has been granted GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator(IX).	• The firm has mentioned film-coated tablet with seal coat and modified release coat. Upon clarification, the firm revised the coating to enteric coating without fee. However, the reference product has an outer protective coat consisting of a combination of acrylic based resins, Eudragit S (methacrylic acid and methyl methacrylate copolymer (1:2), NF) and Eudragit L (methacrylic acid and methyl methacrylate copolymer (1:1), NF). The inner coat consists of an acrylic based resin, Eudragit S, which dissolves at pH 7 or greater, releasing mesalamine in the terminal ileum and beyond for topical anti- inflammatory action in the colon.

	Previous decision	The Board in its 289th meeting deferred the case for clarification from the firm.
	Evaluation by PEC	• The firm submitted revised Master formula and manufacturing outlines. • The firm initially applied for modified release tablet. The firm revised the label claim to delayed release tablet, then to modified release tablet and finally to delayed release tablet.
	Decision: Deferrred for submission of fee of Rs. 20,000/- for revision of label claim as per reference product.	
846.	**Name and address of manufacturer / Applicant**	**Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Mesaco Tablet 400mg
	Composition	Each delayed release tablet contains: Mesalazine…….400mg
	Diary No. Date of R& I & fee	Dy No. 6961: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ASACOL® HD (mesalamine) delayed-release tablets, for oral use. **MHRA** approved Octasa 400 mg Modified Release Tablets. MHRA approved
	Me-too status	Coltab Tablet 400mg. Reg. No. 41652
	GMP status	The firm has been granted GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator(IX).	• The firm has mentioned film-coated tablet with seal coat and modified release coat. Upon clarification, the firm revised the coating to enteric coating without fee. However, the reference product has an outer protective coat consisting of a combination of acrylic based resins, Eudragit S (methacrylic acid and methyl methacrylate copolymer (1:2), NF) and Eudragit L (methacrylic acid and methyl methacrylate copolymer (1:1), NF). The inner coat consists of an acrylic based resin, Eudragit S, which dissolves at pH 7 or greater, releasing mesalamine in the terminal ileum and beyond for topical anti- inflammatory action in the colon.
	Previous decision	The Board in its 289th meeting deferred the case for clarification from the firm.
	Evaluation by PEC	• The firm submitted revised Master formula and manufacturing outlines. • The firm initially applied for modified release tablet. The firm revised the label claim to delayed release tablet, then to modified release tablet and finally to delayed release tablet.
	Decision: Deferrred for submission of fee of Rs. 20,000/- for revision of label claim as per reference product.	
847.	Name and address of manufacturer/ Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name + Dosage Form + Strength	Arcoxone 2gm Injection IV
	Composition	Each Vial Contains: Ceftriaxone as sodium…2g
	Diary No. Date of R & I & fee	Dy. No. 30415; 10.09.2018 PKR. 20,000/-; 10.09.2018

	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PCA
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 2 g powder for solution for injection/infusion. MHRA approved
	Me-too status	Cefast 2g Injection I.V. Reg. No. 82281
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 12.12.2017.
	Remarks of the Evaluator(IX)	Submit clear and complete manufacturing outlines, including sterile filling/terminal sterilization and packing process
	Previous decision	The Board in its 293rd meeting deferred the case for submission of clear and complete manufacturing outlines, including sterile filling/terminal sterilization and packing process.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
848.	**Name and address of manufacturer /Applicant**	**M/s Medizan Laboratories (Pvt) Ltd Plot no. 313, Industrial Triangle Kahuta Road Islamabad, Pakistan.**
	Brand Name +Dosage Form + Strength	PARACORD TABLETS
	Composition	Each tablet contains:- Paracetamol…..500mg Codeine phosphate ……..15mg
	Diary No. Date of R & I & fee	Dy.No. 16281: 07-03-2019 Rs. 20,000/- dated 07-03-2019
	Pharmacological Group	Analgesics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, **Price as per SRO**
	Approval status of product in Reference Regulatory Authorities.	Co-codamol (8mg/500 mg, 15mg/500 mg, 30mg/500 mg) Tablets**. MHRA Approved**
	Me-too status	CODOGESIC **15mg/500 mg tablet.** Reg. No.: 028956
	GMP status	New section
	Remarks of the Evaluator(IX)	• The reference product contains **Codeine phosphate hemihydrate ….15mg without equivalency. Correction is required.**
	Previous decision	The Board in its 294th meeting deferred the case for revision of label claim as per reference product along with submission of requisite fee.
	Evaluation by PEC	The firm submitted **Codeine phosphate….15mg instead of Codeine phosphate hemihydrate ….15mg with submission of Rs. 5000/- fee.**
	Decision: Deferred for revision of label claim from Codeine phosphate….15mg to Codeine phosphate hemihydrate ….15mg.	
849.	Name and address of manufacturer / Applicant	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad; contract manufacturing by M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	BeCef 100mg/5ml Suspension
	Composition	Each 5ml Reconstituted Suspension Contains: Cefixime Trihydrate Eq. to Cefixime…100mg
	Diary No. Date of R& I & fee	Dy. No. 32778; 03-10-2018, PKR: 50,000/-; 03-10-2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	30ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Eliximе Dry Suspension 100mg. Reg. No. 53729
	GMP status	Applicant: The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance. Manufacturer: The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator(IX).	• The firm did not submit list of approved products of applicant for contract manufacturing. • The firm submitted list of 06 applied products for contract manufacturing. • The firm did not submit list of all approved sections of applicant.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of list of approved products of applicant for contract manufacturing. • Submission of list of approved sections. • Capacity assessment of M/s Novamed as decided earlier by Registration Board
	Evaluation by PEC	• The firm submitted list of 14 sections. • The firm submitted that they have no contract manufacturing agreement with any other firm.
	Decision: Approved.	
850.	Name and address of manufacturer / Applicant	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad; contract manufacturing by** **M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	BeCef 200mg/5ml Suspension
	Composition	Each 5ml Reconstituted Suspension Contains: Cefixime Trihydrate Eq. to Cefixime…200mg
	Diary No. Date of R& I & fee	Dy. No. 32779; 03-10-2018 PKR: 50,000/-; 03-10-2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Eliximе Dry Suspension 200mg. Reg. No. 53730
	GMP status	Applicant: The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance. Manufacturer: The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator(IX).	• The firm did not submit list of approved products of applicant for contract manufacturing. • The firm submitted list of 06 applied products for contract manufacturing. • The firm did not submit list of all approved sections of applicant.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of list of approved products of applicant for contract manufacturing.

		• Submission of list of approved sections. • Capacity assessment of M/s Novamed as decided earlier by Registration Board
	Evaluation by PEC	• The firm submitted list of 14 sections. • The firm submitted that they have no contract manufacturing agreement with any other firm.
	Decision: Approved.	
851.	Name and address of manufacturer / Applicant	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad; contract manufacturing by M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	BeCef 200mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…200mg
	Diary No. Date of R& I & fee	Dy. No. 32936; 03-10-2018 PKR: 50,000/-; 03-10-2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's, 10's; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	CEFIXIMA NORMON 200 mg HARD CAPSULES EFG. CIMA approved
	Me-too status	CEFIXIMA NORMON 200 mg HARD CAPSULES EFG. Reg. No. 34664
	GMP status	Applicant: The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance. Manufacturer: The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator(IX).	• The firm did not submit list of approved products of applicant for contract manufacturing. • The firm submitted list of 06 applied products for contract manufacturing. • The firm did not submit list of all approved sections of applicant.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of list of approved products of applicant for contract manufacturing. • Submission of list of approved sections. • Capacity assessment of M/s Novamed as decided earlier by Registration Board
	Evaluation by PEC	• The firm submitted list of 14 sections. • The firm submitted that they have no contract manufacturing agreement with any other firm.
	Decision: Approved.	
852.	Name and address of manufacturer / Applicant	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad; contract manufacturing by M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	BeCef 400mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…400mg
	Diary No. Date of R& I & fee	Dy. No. 32780; 02-10-2018 PKR: 50,000/-; 02-10-2018
	Pharmacological Group	Third-generation cephalosporins

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) 400mg capsules, for oral. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule. Reg. No. 82219
	GMP status	Applicant: The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance. Manufacturer: The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator(IX).	• The firm did not submit list of approved products of applicant for contract manufacturing. • The firm submitted list of 06 applied products for contract manufacturing. • The firm did not submit list of all approved sections of applicant. • First page of Form 5 has not been signed. • Revise "Cefixime Trihydrate Eq. to Cefixime" to "Cefixime Trihydrate" in Master formula only
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of list of approved products of applicant for contract manufacturing. • Submission of list of approved sections. • Capacity assessment of M/s Novamed as decided earlier by Registration Board
	Evaluation by PEC	• The firm submitted list of 14 sections. • The firm submitted that they have no contract manufacturing agreement with any other firm.
	Decision: Approved.	
853.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Mensodol Tablet 500/25mg
	Composition	Each film-coated tablet contains: Paracetamol…500mg Pamabrom…25mg
	Diary No. Date of R& I & fee	Dy No. 15549: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Anilides + Pamabrom (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Back Aid Max, OTC product) which is available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fb9a5647-b7c9-4820-b148-91060e34cb83
	Me-too status	Women's Tylol Caplets. Reg. No. 62787
	GMP status	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator(IX)	•Form 5 is different in some points from the approved one. •Justification is required about 3% excess. •Provide proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.

		• The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Previous decision	The Board in its 289th meeting deferred the case the following: • Justification is required about 3% excess. • Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Evaluation by PEC	• The firm submitted that the overage was mentioned mistakenly. • The firm submitted that the label claim is film-coated tablet. • Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Previous decision	• The Board in its 292nd meeting deferred the case for Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Evaluation by PEC	• The firm provided reference of "Back Aid Max, OTC product) which could be confirmed.
	Previous decision	• The Board in its 295th meeting deferred the case for proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Evaluation by PEC	• The firm provided reference of "Back Aid Max, OTC product) which is available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fb9a5647-b7c9-4820-b148-91060e34cb83
	Decision: Approved.	
854.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Glytide 200mg Injection
	Composition	Each Vial Contains: Teicoplanin…200mg
	Diary No. Date of R & I & fee	Dy. No. 32793; 02.10.2018 PKR. 20,000/-; 01.10.2018
	Pharmacological Group	Glycopeptide antibacterials
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1's (glass vial); As per policy of MoH
	Approval status of product in Reference Regulatory Authorities	Teicoplanin 200 mg, powder for solution for injection/infusion or oral solution. **MHRA** approved
	Me-too status	Planin 200mg Injection. Reg. No. 55188
	GMP status	As above
	Remarks of the Evaluator(IX)	•
	Previous decision	• The Board in its 293rd meeting deferred the case for Deferred for confirmation of manufacturing process (powder filling or lyophilization) and requisite facility.

	Evaluation by PEC	• The firm submitted revised manufacturing outlines, which depicts that the product is manufactured by the process of lyophilisation.
	Decision: Approved with innovator's specification.	
855.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Glytide 400mg Injection
	Composition	Each Vial Contains: Teicoplanin…400mg
	Diary No. Date of R & I & fee	Dy. No. 32793; 02.10.2018 PKR. 20,000/-; 01.10.2018
	Pharmacological Group	Glycopeptide antibacterials
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1's (glass vial); As per policy of MoH
	Approval status of product in Reference Regulatory Authorities	Teicoplanin 400 mg, powder for solution for injection/infusion or oral solution. **MHRA** approved TARGOCID teicoplanin 400mg lyophilized powder for injection vial with diluent ampoule. TGA approved.
	Me-too status	Asist 400mg Injection. Reg. No. 50694
	GMP status	As above
	Remarks of the Evaluator(IX)	• First page of Form 5 has been signed by quality control manager.
	Previous decision	• The Board in its 293rd meeting deferred the case for confirmation of manufacturing process (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines, which depeicts that the product is manufactured by the process of lyophilisation.
	Decision: Approved with innovator's specification.	
856.	**Name and address of manufacturer / Applicant**	**M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Vildamed 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy No. 19150: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. **TGA** approved
	Me-too status	GALVUS MET 50MG/850MG TABLETS. Reg. No. 66106
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator(IX).	• **The shelf-life of reference product in TGA is 18 months.** • The name of signatory is not present on the form 5.
	Pervious decision	The Board in its 291st meeting deferred the case for revision of salt form in line with the reference product along with submission of applicable fee.
	Evaluation by PEC	• The firm has revised metformin to Metformin HCl along with submission of Rs. 5000/- fee.

		• **Revision of Form5 and Master Formula is still required.**
	Pervious decision	• The Board in its 293rd meeting deferred the case for salt form in Form5 and Master Formula.
	Evaluation by PEC	• The firm revised salt form in Form5 and Master Formula.
	Decision: Approved with innovator's specification and 18 months shelf life.	
857.	**Name and address of manufacturer / Applicant**	**M/s Alen Pharmaceuticals (Pvt) Ltd. 138-A, Nowshehra Industrial Estate, Risalpur, KPK. By M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Brand Name +Dosage Form + Strength	S-Alen 40mg Infusion
	Composition	Each Vial Contains: Esomeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 27714: 13.08.2018 PKR 50,000/-: 10.08.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	as fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	Applicant: Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Manufactuer: Inspection of M/s Welwrd Pharmaceuticals was conducted on 12.11.2018, wherein the following sections of the firm were considered to be operating at satisfactory level of GMP. i) Tablet Section (General/antibiotics) ii) Liquid injectable section (General/antibiotics) iii) Dry injectable section (General/antibiotics) iv) Dry powder injectable (cephalosporins) While the remaining sections viz Capsule general, dry powder suspension general and Sachet sections were observed with certain shortcomings that need to be rectified. The firm M/s Alen Pharma was inspected on 31.05.2018, **where no conclusion has been made thereof.**
	Remarks of the Evaluator(IX).	• The firm revised the address to M/s Alen Pharmaceuticals (Pvt) Ltd. 138-A, Nowshehra Industrial Estate, Risalpur, KPK. • Scanned signatures are placed in the Undertaking at the end of Form 5. • The salt form was correct in master Formula. However, the firm revised 'Esomeprazole' to 'Esomeprazole as sodium' in label claim. • List of already approved product for contract manufacturing of M/s Alen Pharmaceuticals Pvt Ltd is required. • List of applied product for contract manufacturing of M/s Alen Pharmaceuticals Pvt Ltd is required. • List of approved sections of M/s Alen Pharmaceuticals Pvt Ltd is required.
	Pervious decision	The Board in its 293rd meeting deferred the case for: • Submission of list of approved products of applicant for contract manufacturing. • Submission of list of approved sections of M/s Alen Pharma.

		• List of applied products for contract manufacturing of M/s Alen Pharma. • Submission of fee for revising the label claim of the applied product.
	Evaluation by PEC	The firm submitted: • List of 04 approved sections • List of 03 approved products • List of 17 applied products • Rs. 5000/- fee.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals Pvt Ltd. Risalpur.	
858.	**Name and address of manufacturer/Applicant**	**M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name + Dosage Form + Strength	Opidol 100mg/2ml Injection
	Composition	Each 2ml ampule contains: Tramadol hydrochloride….100mg
	Diary No. Date of R & I & Fee	Dy No. 15610: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other opioids
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	2mlx10's;, 2mlx30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Tramadol 50mg/ml Solution for Injection or Infusion (2ml). MHRA approved
	Me-too Status	Welmadol Injection (2ml). Reg. No. 52629 (deos not show ampule or vial)
	GMP Status	The firm was inspected on 22.06.2020 with the following conclusion: In light of above the firm can be rated as complying GMP standards as per Schedule B-II of Drugs (LR&A) Rules, 1976. However, cGMP is a continual process of improvement for which the above stated points of improvement have been agreed upon by the management.
	Remarks of the Evaluator[IX]	•
	Pervious decision	The Board in its 289th meeting deferred the case for consideration on its turn as neither Narcotic or Psychotropic as per INCB
	Evaluation by PEC	•
	Decision: Deferred for consideration on its turn.	
859.	**Name and address of manufacturer / Applicant**	**M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name + Dosage Form + Strength	Nilbo 10mg/ml Injection
	Composition	Each ml contains: Nalbuphine hydrochloride….10mg
	Diary No. Date of R & I & Fee	Dy No. 15609: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Morphinan derivatives
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufactuer's specifications.
	Pack Size & Demanded Price	2x5 ampule PVC contour cellular package 1 contour cellular in a carton box.
	Approval Status of product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved
	Me-too Status	Nalburax Injection. Reg. No. 28830 (deos not show ampule or vial)

	GMP Status	The firm was inspected on 22.06.2020 with the following conclusion: In light of above the firm can be rated as complying GMP standards as per Schedule B-II of Drugs (LR&A) Rules, 1976. However, cGMP is a continual process of improvement for which the above stated points of improvement have been agreed upon by the management.
	Remarks of the Evaluator(IX)	• Clarification is required about the pack size.
	Pervious decision	The Board in its 289th meeting deferred the case for consideration on its turn as neither Narcotic or Psychotropic as per INCB
	Evaluation by PEC	•
	Decision: Deferred for consideration on its turn.	
860.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Propex 1g/100ml Infusion
	Composition	Each 100ml Contains: Acetaminophen…1g
	Diary No. Date of R& I & fee	Dy No. 30578: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Anilides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	Provas Infusion 10mg/ml. No. 53223 (filled volume not specified)
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5.
	Previous decision	The Board in its 293rd meeting deferred the case for completion of Form 5.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form is missing.
	Previous decision	The Board in its 295th meeting deferred the case for submission of undertaking of Form-5.
	Evaluation by PEC	The firm submitted undertaking at the end of Form.
	Decision: Approved.	
861.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Droxipal 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…125mg
	Diary No. Date of R& I & fee	Dy No. 30585: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Biodroxil 125 mg /5 ml - Pulver zur Herstellung einer Suspension zum Einnehmen (Biodroxil 125 mg / 5 ml - Powder for oral suspension). **AGES** approved
	Me-too status	Evacef Suspension 125mg. Reg. No. 11213

	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • The firm has mentioned granulation process in the manufacturing outlines. Justification that the international reference product is the form of granule for suspension, was asked from the firm. The firm did not justify.
	Previous decision	The Board in its 293rd meeting deferred the case for clarification/submission of the manufacturing outline in line with the reference product.
	Evaluation by PEC	The firm submitted biodroxil as reference product and stated that the product mentioned that it is granule for suspension. The said product could not be verified.
	Previous decision	The Board in its 295th meeting deferred the case for submission of manufacturing outline in line with reference product
	Evaluation by PEC	The matter shall be deliberated by the Board regarding the granule or powder for suspension and fee thereof.
	Decision: Deferred for further deliberation regarding formulation in line with reference product.	
862.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Droxipal 250mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…250mg
	Diary No. Date of R& I & fee	Dy No. 30586: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil 250 mg/5 ml **powder** for oral suspension. USFDA approved. Cefadroxil 250 mg/5 ml **granules** for oral suspension. MHRA approved
	Me-too status	Evacef Suspension 250mg. Reg. No. 11214
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	Form 5 has not been submitted.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of Form 5.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of form is missing.
	Previous decision	The Board in its 295th meeting deferred the case for submission of undertaking of Form-5.
	Evaluation by PEC	The firm submitted undertaking at the end of Form.
	Decision: Deferred for further deliberation regarding formulation in line with reference product.	
863.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Droxipal 500mg Capsule
	Composition	Each capsule contains: Cefadroxil Monohydrate Eq. to Cefadroxil…500mg
	Diary No. Date of R& I & fee	Dy No. 30588: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil 500 mg Capsules. MHRA approved
	Me-too status	Sokxil 500mg Capsules. Reg. NO. 54925
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • The firm has mentioned granulation process in the manufacturing outlines. Justification that the international reference product is the form of granule for suspension, was asked from the firm. The firm did not justify. • Evidence of me-too product (name and registration number) approved by DRAP is required.
	Previous decision	The Borad in its 293rd meeting deferred the case for the following: • Clarification/submission of the manufacturing outline inline with the reference product. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC	The firm has applied for Droxipal 500mg Capsule, however, the case was mistakenly presented as Droxipal 500mg/5ml suspension.
	Decision: Approved.	
864.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Famopal 20mg Tablet
	Composition	Each film-coated tablet contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy No. 30579: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AUSFAM famotidine 20mg and 40mg tablet, film-coated blister pack. TGA approved
	Me-too status	Welcid-20mg Tablet film-coated. Reg. No. 81681
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	• Form 5 has not been submitted. • You have mentioned methylene chloride in the coating composition. Justify its safety.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of form 5. • Use of banned excipient that is methylene chloride in coating.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form 5 is missing. The firm revised the coating composition.
	Previous decision	The Board in its 295th meeting deferred the case for submission of undertaking of Form-5.

	Evaluation by PEC	The firm submitted undertaking at the end of Form.
	Decision: Approved.	
865.	**Name and address of manufacturer / Applicant**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Famopal 40mg Tablet
	Composition	Each film-coated tablet contains: Famotidine…40mg
	Diary No. Date of R& I & fee	Dy No. 30580: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AUSFAM famotidine 20mg and 40mg tablet, film-coated blister pack. TGA approved
	Me-too status	Famitol 40mg Tablet film-coated. Reg. No. 85770
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator(IX).	• Form 5 has not been submitted. • You have mentioned methylene chloride in the coating composition. Justify its safety.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of form 5. • Use of banned excipient that is methylene chloride in coating.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form 5 is missing. The firm revised the coating composition.
	Previous decision	The Board in its 295th meeting deferred the case for submission of undertaking of Form-5.
	Evaluation by PEC	The firm submitted undertaking at the end of Form.
	Decision: Approved.	
866.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Solicin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Diary No. Date of R & I & fee	Dy. No. 1461; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 5mgtablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 5mg. Reg No. 81958
	GMP status	The firm was inspected on 13.09.2019 the following recommendations: The panel of inspector recommends the renewal of M/s Pharmix Laboratories Pvt Ltd. Located at 21 Km, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad.
	Remarks of the Evaluator(IX)	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed

		undertaking at the end of Form 5. The firm submitted undertaking only.
	Previous decision	The Board in its 295th meeting deferred the case for submission of complete Form 5.
	Evaluation by PEC	• The firm submitted complete enclosure of Form 5.
	Decision: Approved with innovator's specification.	
867.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Solicin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Diary No. Date of R & I & fee	Dy. No. 1462; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 10mg tablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 10mg. Reg No. 81959
	GMP status	As for above case
	Remarks of the Evaluator(IX)	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Previous decision	The Board in its 295th meeting deferred the case for submission of complete Form 5.
	Evaluation by PEC	• The firm submitted complete enclosure of Form 5.
	Decision: Approved with innovator's specification.	
868.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Prelin 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R & I & fee	Dy. No. 1460; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	As for above case
	Remarks of the Evaluator(IX)	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Previous decision	The Board in its 295th meeting deferred the case for submission of complete Form 5.
	Evaluation by PEC	• The firm submitted complete enclosure of Form 5.
	Decision: Approved with innovator's specification.	
869.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Alcox 60mg Tablet

	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R & I & fee	Dy. No. 4422; 31.01.2019 PKR. 20,000/-; 31.01.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA etoricoxib 60mg film-coated tablet. **TGA** approved
	Me-too status	Gencox 60mg Tablets film-coated. Reg. No. 78839
	GMP status	As for above case
	Remarks of the Evaluator(IX)	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Previous decision	The Board in its 295th meeting deferred the case for submission of complete Form 5.
	Evaluation by PEC	• The firm submitted complete enclosure of Form 5.
	Decision: Approved with innovator's specification.	
870.	**Name and address of manufacturer / Applicant**	**Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Pantozon Tablet 40mg
	Composition	Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate)……40mg
	Diary No. Date of R& I & fee	Dy No. 7145: 23.02.2018 PKR 20,000/-: 23.02.2018 PKR 20,000/-: 25.09.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets 40mg, for oral use. USFDA approved
	Me-too status	PROTIUM GASTRO RESISTANT TABLETS 40mg. Reg. No. 21039
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator(IX).	• The brand, generic or strength has not been mentioned on the fee challan. The firm submitted undertaking • The firm revised the dosage form from capsule to delayed release tablet with submission of Rs. 20000/- fee. • Correction of pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor. • The reference product has a sub-coating above which enteric coating is present. The submitted dossier does not depict the same.
	Previous decision	The Board in its 293rd meeting deferred the case for for clarification of composition of applied product regarding the sub-coating above which the enteric coating is present as per the composition of the reference product.
	Evaluation by PEC	The firm revised pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor and revised the manufacturing outlines.

	Previous decision	The Board in its 295th meeting deferred the case for submission of fee for revision of master formula.
	Evaluation by PEC	• The firm has already submitted fee of Rs. 20000/- of revision of dosage form. The Board may review its decision
	Decision: Approved with innovator's specification.	
871.	**Name and address of manufacturer / Applicant**	**Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Pantozon Tablet 20mg
	Composition	Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate)……20mg
	Diary No. Date of R& I & fee	Dy No. 7144: 23.02.2018 PKR 20,000/-: 23.02.2018 PKR 20,000/-: 25.09.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Panzium (pantoprazole base) capsules 20mg. 60482
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator(IX).	• The brand, generic or strength has not been mentioned on the fee challan. The firm submitted undertaking • The firm revised the dosage form from capsule to delayed release tablet with submission of Rs. 20000/- fee. • Correction of pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor. • The reference product has a sub-coating above which enteric coating is present. The submitted dossier does not depict the same.
	Previous decision	The Board in its 293rd meeting deferred the case for for clarification of composition of applied product regarding the sub-coating above which the enteric coating is present as per the composition of the reference product.
	Evaluation by PEC	The firm revised pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor and revised the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for submission of fee for revision of master formula.
	Evaluation by PEC	• The firm has already submitted fee of Rs. 20000/- of revision of dosage form. The Board may review its decision
	Decision: Approved with innovator's specification.	
872.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winlor 8mg Injection
	Composition	Each Vial Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 1153 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5

	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved
	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator(IX)	The firm submitted list of 03 products registered for contract manufacturing.
	Previous decision	The Board in its 295th meeting deferred the case for for following: • Confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise. • DML status of M/s Alen
	Evaluation by PEC	• The firm submitted that lyphlization is being performed by M/s Bio-Lab (Pvt) Ltd.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals Pvt Ltd.	
873.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winrose Injection 100mg/5ml
	Composition	Each ampoule contains: Iron sucrose…100mg
	Diary No. Date of R & I & fee	Dy. No. 1152 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator(IX)	• Revise the label claim and salt from in line with the reference product along with submission of applicable fee. • The firm submitted list of 03 products registered for contract manufacturing.

	Previous decision	The Board in its 295th meeting deferred the case for for following: • Confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise. • DML status of M/s Alen
	Evaluation by PEC	• The firm did not submit copy of DML. • The reference product contains iron(III) hydroxide sucrose complex which is equivalent to 20mg/ml elemental Iron. Iron sucrose is gerneric term used for iron(III) hydroxide sucrose complex in TGA Australia.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals Pvt Ltd.	
874.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zolid 600mg/300ml Infusion
	Composition	Each Vial Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 1151 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator(IX)	• The firm submitted list of 03 products registered for contract manufacturing.
	Previous decision	The Board in its 295th meeting deferred the case for DML status of M/s Alen
	Evaluation by PEC	• The firm did not submit copy of DML.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals Pvt Ltd.	
875.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Locrim 400mg Infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 1154; 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO

	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator(IX)	• The firm submitted list of 03 products registered for contract manufacturing.
	Previous decision	The Board in its 295th meeting deferred the case for DML status of M/s Alen
	Evaluation by PEC	• The firm did not submit copy of DML.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals Pvt Ltd.	
876.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Omora Insta 40/1680 mg Sachet
	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R & I & fee	Dy. No. 1681; 14.01.2019 PKR. 20,000/-; 14.01.2019
	Pharmacological Group	USP
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. approved by US-FDA
	Me-too status	Risek Insta Sachet by Getz Pharma (Pvt.) Ltd., Karachi Reg. No. 58548
	GMP status	The firm has been issued GMP certificate on the bsis of inspection dated 21.05.2019.
	Remarks of the Evaluator(IX)	• The firm has added 3% overage of Omeprazole with the justification to compensate loss during manufacturing.
	Previous decision	• The Board in its 295th meeting deferred the case for scientific rationale for addition of 3% overage.
	Evaluation by PEC	• The firm submitted that overage is added to compensate the potency loss during manufacturing.
	Decision: Deferred for scientific rationale for addition of overage.	
877.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Ketafen Gel Extra
	Composition	Contains: Diclofenac diethylamine…2.32% w/w
	Diary No. Date of R & I & fee	Dy. No. 2902; 22.01.2019 PKR. 20,000/-; 21.01.2019
	Pharmacological Group	Other dermatologicals
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	as per SRO

	Approval status of product in Reference Regulatory Authorities.	VOLTAROL EXTRA STRENGTH EMULGEL 2.32% GEL. MHRA approved VOLTAREN EMULGEL JOINT PAIN EXTRA STRENGTH (11.6% w/w, 2.32 w/w). Health Canada approved
	Me-too status	Sofac Gel 2% (DiclofenacDiethylamine23.20mgeq.toDiclofenac…20mg). Reg. No. 60356
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 21.05.2019.
	Remarks of the Evaluator(IX)	• The firm revised the label claim from Diclofenac diethylamine…2% to Diclofenac diethylamine…2.32%, and claimed submission of Rs. 5000/- fee. The fee challan and endorsement form STO is missing. The fee for revision of strength may also be clarified by the registration Board. • Clarify whether the strength is w/w or w/v.
	Previous decision	• The Board in its 295th meeting deferred the case for submission of fee for revision of formulation.
	Evaluation by PEC	• The firm submitted illegible copy of fee challan without endorsement from STO.
	Decision: Deferred for submission of fee challan as per proceedure.	
878.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Vomiron 4mg Tablets
	Composition	Each film-coated tablet contains: Ondansetron as HCl dihydrate…4mg
	Diary No. Date of R& I & fee	Dy. No. 40266: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg Film-coated Tablets. MHRA approved
	Me-too status	Ondan Tablet film-coated 4mg. Reg No. 82656
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• You have mentioned coating composition in the master formula. Revise the label claim accordingly. • Revise "Ondansetron HCl as dihydrate" to "Ondansetron as HCl dihydrate" in the label claim. Correction is also required in the master formula along with adjustment of weight of API as per salt factor. • Justify the addition of overage.
	Previous decision	The Board in its 295th meeting deferred the case for: • Revision of formulation as per the reference product along with submission of fee for revision of formulation • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Justification of addition of overage
	Evaluation by PEC	• The firm had mentioned coating composition in the master formula. The firm revised the label claim from "Each Tablet Contains" to "Each film-coated tablet contains". And submitted Rs. 5000/- fee.

		• The firm revised "Ondansetron HCl as dihydrate" to "Ondansetron as HCl dihydrate" in the label claim. Correction is also required in the master formula along with adjustment of weight of API as per salt factor. • The firm submitted that there is no overage.
	Decision: Deferred for revision of Ondansetron HCl as dihydrate to Ondansetron HCl dihydrate in master formula only along with adjustment of weight of API as per salt factor.	
879.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Caraceclo 100mg Tablets
	Composition	Each film-coated tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy. No. 40268: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg film-coated Tablets (aceclofenac). MHRA approved
	Me-too status	Acenac 100Mg Tablets. Reg. No. 39336
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• The firm revised the salt form to aceclofenac from aceclofenac sodium without submission of applicable fee. • The firm has applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula.
	Previous decision	The Board in its 295th meeting deferred the case for revision of formulation as per the reference product along with submission of fee for revision of formulation.
	Evaluation by PEC	• The firm had already revised the documents and now submitted Rs. 5000/- fee.
	Decision: Approved with innovator's specification.	
880.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Schizonil 200mg Tablets
	Composition	Each film-coated tablet Contains: Quetiapine as fumarate…200mg
	Diary No. Date of R& I & fee	Dy. No. 40268: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine (as fumarate) 200mg Film-coated Tablets. MHRA approved
	Me-too status	Etal 200mg Tablet Tablet. Reg. No. 80380
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• The firm revised "quetiapine" to "quetiapine as fumarate" without submission of fee. • The firm had applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula. • Brand name and dosage form has not been mentioned in the fee challan.

	Previous decision	The Board in its 295th meeting deferred the case for for following: • Revision of formulation as per the reference product along with submission of fee for revision of formulation. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm had already revised the documents and now submitted Rs. 5000/- fee.
	Decision: Approved with innovator's specification.	
881.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ometro 40mg Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy. No. 40267: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec 40 mg hard gastro-resistant capsules. Approved by MHRA
	Me-too status	Omecap Capsule. Reg. No. 84494
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• The label claim is "Each hard gelatin capsule contains: Omeprazole…40mg". The reference product is hard gastro-resistant capsules. The firm was asked to submit source, GMP of source and COA and stability data of three batches of pellets conducted in zone IV-A. The firm did not submit the same. The Boards is requested to clarify the matter of label claim is as well and submission of fee for change thereof.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Source of pellets, along with stability studies data, GMP certificate of pellets manufacturer and differential fee in case of import of pellets. • Revision of label claim as per the reference product.
	Evaluation by PEC	• The firm submitted the source of pellets (M/s Vision Pahrmaceuticals, Islamabad) and submitted Rs. 5000/- fee.
	Decision: Approved.	
882.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Beta-C Cream
	Composition	Each Gram Contains: Betamethasone as dipropionate…0.05% Clotrimazole…1%
	Diary No. Date of R& I & fee	Dy. No. 40882: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antifungal with corticosteroids
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	LOTRISONE® (clotrimazole and betamethasone dipropionate) cream, for topical use (1%/0.05%). USFDA Approved

	Me-too status	Holfungin Cream. Reg. No. 67598
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	Undertaking at the end of Form 5 has not been signed by the production manager and QCM by the QCM and production manager. Brand name and dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.
	Decision: Approved.	
883.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Burn-Off Cream
	Composition	Each Gram Contains: Silver sulphadiazine…1%w/w
	Diary No. Date of R& I & fee	Dy. No. 40884: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Sulfonamides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flamazine Cream 1.0%w/w. MHRA approved
	Me-too status	SILZIN CREAM Reg. No. 21193
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	Undertaking at the end of Form 5 has not been signed by the production manager and QCM. Brand name and dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.
	Decision: Approved.	
884.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rash-Care Cream
	Composition	Each gram contains: Zinc oxide…8.5% w/w Benzalkonium chloride…0.1% w/w
	Diary No. Date of R& I & fee	Dy. No. 40884: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications

	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	RASHNIL CRM (8.5%/1%). Reg. No. 6356
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Brand name and dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting and pharmacological group.	
885.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Olimag-F Capsule
	Composition	Each hard gelatin capsule contains: Fluoxetine as Hydrochloride…25mg Olanzapine…12mg
	Diary No. Date of R& I & fee	Dy. No. 40881: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by US-FDA
	Me-too status	Olanco Capsules. Reg. No. 79387
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Brand name and dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.

	Decision:Approved.	
886.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ompro-S Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…20mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy. No. 40880: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors + antacid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (omeprazole and sodium bicarbonate) capsules (20/1100mg and 40/1100mg) capsule. USFDA approved
	Me-too status	Zogital 20mg Capsules (omeprazole base). Reg. No. 64391
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Brand name and dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.
	Decision: Approved with innovator's specification.	
887.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ompro-S Plus Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…40mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy. No. 40879: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors + antacid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (omeprazole and sodium bicarbonate) capsules (20/1100mg and 40/1100mg) capsule. USFDA approved
	Me-too status	Omfast 40/1100mg Capsule. Reg. No. 82717
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• Brand name and dosage form has not been mentioned in the fee challan. • Undertaking at the end of Form 5 has not been signed by the production manager and QCM by the porudction manager and QCM.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge.

		• Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.
	Decision: Approved with innovator's specification.	
888.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lorncam 8mg Tablets
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy. No. 40885: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator(IX)	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Dosage form has not been mentioned in the fee challan.
	Previous decision	The Board in its 295th meeting deferred the case for following: • Submission of undertaking of Form 5 signed by production incharge and QC incharge. • Clarification why the brand name and dosage form is not mentioned on fee challan.
	Evaluation by PEC	• The firm submitted undertaking of Form 5. • The firm submitted that by mistake they have not mentioned dosage form and brand name on the fee challan.
	Decision: Approved.	
889.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Feloxacine Tablets 400mg
	Composition	Each film-coated tablet contains: Lomefloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 7379; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Maxaquin® lomefloxacin (as hydrochloride) film-coated tablets 400mg. TGA approved
	Me-too status	Lomedin Tablets 400mg. Reg No. 28668 (does not depict film-coating)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Revise Lomefloxacin Hcl to Lomefloxacin as Hcl in the label claim

		• You have claimed USP specifications. Provide proof that the finished product is available in USP.
	Previous decision	• The Board in tis 295th meeting deferred the case for revision of formulation as per reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised the formulation as per reference product al0ong with submission of Rs. 5000/-. • The firm claimed BP specifications. The product is not available in BP.
	Decision: Approved with innovator's specification.	
890.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Fixetin Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Fluoxetine as HCL…10mg
	Diary No. Date of R & I & fee	Dy. No. 8549; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SARAFEM (fluoxetine as hydrochloride 10mg, 15mg, 20mg uncoated tablets). USFDA approved
	Me-too status	Futine 10 mg Tab. Reg. No. 44602 (Fluoxetine HCL…10mg)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Provide proof of reference product (film-coated tablet) in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the formulation (label claim, composition and manufacturing outlines) to uncoated tablet, along with submission of applicable fee. • Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Previous decision	• The Board in tis 295th meeting deferred the case revision of formulation as per reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm did not revise the formulation as per reference product, but submitted Rs. 5000/- fee.
	Decision: Deferred for revision of formulation as per reference product.	
891.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Desfaxine 100mg Tablets
	Composition	Each extended release tablet contains Desvenlafaxine as succinate monohydrate …100mg
	Diary No. Date of R & I & fee	Dy. No. 8551; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pristiq extended release tablets 100mg (film-coated). USFDA approved
	Me-too status	Denla XR 100mg Tablet. Reg. No. 70434 (Does not depict coating)
	GMP status	As above

	Remarks of the Evaluator(IX)	• Revise Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim
	Previous decision	• The Board in tis 295th meeting deferred the case revision of formulation as per reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim.
	Decision: Approved.	
892.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Desfaxine 50mg Tablets
	Composition	Each extended release tablet contains Desvenlafaxine as succinate monohydrate …50mg
	Diary No. Date of R & I & fee	Dy. No. 8550; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pristiq extended release tablets 50mg (film-coated). USFDA approved
	Me-too status	Denla XR 50mg Tablet. Reg. No. 70433 (Does not depict coating)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Revise Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim
	Previous decision	• The Board in tis 295th meeting deferred the case revision of formulation as per reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim.
	Decision: Approved.	
893.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/10mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……5mg Atorvastatin as calcium trihydrate……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 40763 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Zodip Plus 10 Tablet. Reg. No. 59794
	GMP status	GMP Inspection of the firm was conducted on 04-03-2019 with the following conclusion:

		All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing □ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of fee for revision of salt form.	
894.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/20mg
	Composition	Each film coated tablet contains Amlodipine as besylate……..5mg Atorvastatin as calcium trihydrate……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 40764 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Zodip Plus 20 Tablet. Reg. No. 59795
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing □ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of applicable fee for revision of salt form.	
895.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/40mg

	Composition	Each Film coated tablet contains Amlodipine as besylate……5mg Atorvastatin as calcium trihydrate……40mg
	Diary No. Date of R& I & fee	Dy. No. 40765 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Co-Atorap 5/40 Tablet. Reg. No. 55142 (does not depict film-coating)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing • □ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of applicable fee for revision of salt form.	
896.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/10mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……10mg
	Diary No. Date of R& I & fee	Dy. No. 40766 : 06.12.2018, Rs.20`,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Corsafe AT 10/10 Tablets. Reg. No. 68320
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing

		□ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of fee for revision of salt form.	
897.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/20mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……20mg
	Diary No. Date of R& I & fee	Dy. No. 40767 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Corsafe AT 10/20 Tablets. Reg. No. 68321
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing □ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of fee for revision of salt form.	
898.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/40mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……40mg
	Diary No. Date of R& I & fee	Dy. No. 40768 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved

	Me-too status	Co-Atorap 10/40 Tablet. Reg. No. 50589 (does not reveal film-coating)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred for following: □ Submission of complete outline of method of manufacturing □ Revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC	• The firm revised Atorvastatin to Atorvastatin as calcium Trihydrate in Form 5. • The firm submitted revised manufacturing outlines.
	Decision: Deferred for submission of fee for revision of salt form.	
899.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fludecan Injection 25mg/ml
	Composition	Each ml contains Fluphenazine decanoate ……25mg
	Diary No. Date of R& I & fee	Dy. No. 40766 : 06.12.2018, Rs. 20,000: 06.12.2018 Daed 06.12.2018
	Pharmacological Group	Phenothiazines with piperazine structure
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml x 1's Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Modecate Injection 25mg/ml (0.5ml, 1ml, 2ml) for IM use. MHRA Approved
	Me-too status	Fenzitec Depot Injection. Reg. No. 73773
	GMP status	As above
	Remarks of the Evaluator(IX)	• Terminal sterilization process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred for submission of detailed method of sterilization.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
900.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dibilo M 1/500 Tablet
	Composition	Each film-coated tablet contains Glimepride ……..……..1mg Metformin HCl……..……..500mg
	Diary No. Date of R& I & fee	Dy. No. 40769 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Sulfonylureas + Biguanides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76011 GPRIDE-M SR 1/500mg tablet (bilayer). Reg. No. 76306
	GMP status	As above

	Remarks of the Evaluator[IX]	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim and submission of applicable is required. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Fee for revision of formulation shall be discussed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
901.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dibilo M 2/500 Tablet
	Composition	Each film-coated tablet contains Glimepride ……..2mg Metformin HCl……..500mg
	Diary No. Date of R& I & fee	Dy. No. 40770 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Biguanide / Sulphonylurea
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76012 GPRIDE-M SR 2/500mg tablet (bilayer). Reg. No. 76307
	GMP status	As above
	Remarks of the Evaluator[IX]	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim and submission of applicable is required. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Fee for revision of formulation shall be discussed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
902.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% w/v 10ml Ampoules
	Composition	Each 10ml contains Sodium Chloride……..…90mg

	Diary No. Date of R& I & fee	Dy. No. 40773 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10mlx1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sodium Chloride Injection BP 0.9% w/v in type I clear glass ampoules (2ml, 5ml, 10ml and 20ml). MHRA approved
	Me-too status	Soride of M/s Bosch Pharma
	GMP status	As above
	Remarks of the Evaluator(IX)	• Terminal sterilization is missing in the manufacturing outlines. • The firm has claimed USP specifications. Available in BP.
	Previous decision	The Board in tis 295th meeting deferred for submission of detailed method of sterilization.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
903.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% w/v 2.5ml Ampoules
	Composition	Each 2.5ml contains Sodium Chloride……22.5mg
	Diary No. Date of R& I & fee	Dy. No. 40774 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Sodium Chloride 0.9% Injection (10ml). Reg. No. 84871
	GMP status	As above
	Remarks of the Evaluator(IX)	Provide evidence of approval of applied formulation (same filled volume) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Terminal sterilization is missing in the manufacturing outlines. • The firm has claimed USP specifications. Available in BP.
	Previous decision	The Board in tis 295th meeting deferred for submission of detailed method of sterilization.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
904.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sericalm Injection 50mg/ml
	Composition	Each ml contains Haloperidol as decanoate……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 40775 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Butyrophenone derivatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's Ampoule As per SRO

	Approval status of product in Reference Regulatory Authorities	HALDOL® 50, 100 (haloperidol as decanoate) For IM Injection Only (1ml ampule). USFDA Approved with box warning
	Me-too status	Seredol Depot Injection (1ml). Reg. No. 60600
	GMP status	As above
	Remarks of the Evaluator(IX)	• Revise "Haloperidol decanoate" to "Haloperidol as decanoate" in the label claim • Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of detailed method of sterilization.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised "Haloperidol decanoate" to "Haloperidol as decanoate" in the label claim.
	Decision: Approved.	
905.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorsafe Tablet 4mg
	Composition	Each film coated tablet contains Lornoxicam……4mg
	Diary No. Date of R& I & fee	Dy. No. 40777 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten (Swiss Medic approved)
	Me-too status	Noxilor Tablet. Reg. No. 84039
	GMP status	As above
	Remarks of the Evaluator(IX)	Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
906.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorsafe Tablet 8mg
	Composition	Each film coated tablet contains Lornoxicam……8mg
	Diary No. Date of R& I & fee	Dy. No. 40778 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.

	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
907.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant Tablet 8mg
	Composition	Each Tablet contains Candesartan Cilexetil……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 41953: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 8 mg non-film-coated tablets, for oral use by ANI Pharms Inc. US-FDA approved
	Me-too status	Cansart 8mg Tablets by CCL Pharma. Reg. No. 82665
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
908.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant Tablet 16mg
	Composition	Each Tablet contains Candesartn Cilexetil……..…16mg
	Diary No. Date of R& I & fee	Dy. No. 41954: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 16 mg non-film-coated tablets, for oral use. US-FDA approved
	Me-too status	Cansart Tablets by CCL Pharma. Reg. No. 33953
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
909.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Beca Tablet 60mg
	Composition	Each film-coated Tablet contains: Etoricoxib……60mg
	Diary No. Date of R& I & fee	Dy. No. 41955: 07.12.2018 Rs. 20,000
	Pharmacological Group	Coxibs
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	3 x 10's As per SRO

	Approval status of product in Reference Regulatory Authorities	Etoricoxib 60 mg Film-coated Tablets. MHRA approved
	Me-too status	Eto 60 mg Tablet. Reg. No. 78176
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Provide finished product specifications. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of finished product specification. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee. The firm claimed in-house specifications.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
910.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Samide Tablet 50mg
	Composition	Each filmcoated tablet contains Lacosamide……50mg
	Diary No. Date of R& I & fee	Dy. No. 41956: 07.12.2018 Rs. 20,000
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. MHRA Approved
	Me-too status	Lalap 50mg tablet. Reg. No. 70470
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
911.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Samide Tablet 100mg
	Composition	Each film-caoted tablet contains

		Lacosamide……100mg
	Diary No. Date of R& I & fee	Dy. No. 41956: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Sodium Channel Inactivator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
912.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Kulb Plus Tablet 50mg/12.5mg
	Composition	Each film-coated tablet contains Losartan Potassium ……50mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy. No. 41959: 07.12.2018 Rs.20,000: 07.12.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	FORTZAAR 50 mg / 12.5 mg film-coated tablets. ANSM approved
	Me-too status	Rosar-H Tablets. Reg. No. 64218
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	

913.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 5mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……5mg
	Diary No. Date of R& I & fee	Dy. No. 41960: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 5mg film-coated tablets. MHRA approved
	Me-too status	Rostat 5mg Tablet. Reg. No. 55729
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised Rosuvastatin to Rosuvastatin (as calcium) in the label claim without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
914.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 10mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……10mg
	Diary No. Date of R& I & fee	Dy. No. 41961: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Rosan 10mg Tablet. Reg. No. 81462
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.

		The firm revised Rosuvastatin to Rosuvastatin (as calcium) in the label claim to without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
915.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 20mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……20mg
	Diary No. Date of R& I & fee	Dy. No. 41962: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Rostat 20mg Tablet. Reg. No. 55731
	GMP status	As above
	Remarks of the Evaluator(IX)	Adjust the weight of APIs as per salt factor in master formula only. Provide finished product specifications. Blistering and packing process is missing in the manufacturing outlines. The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing. □ Submission of finished product specification □ Submission of master formulation in line with the reference product
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • The firm revised Rosuvastatin to Rosuvastatin (as calcium) in the label claim to without submission of fee. • Submission of finished product specification is required • Submission of master formulation in line with the reference product is required
	Decision: Deferred for following: • **Fee for revision of salt form.** • **Submission of finished product specification is required.** • **Submission of master formulation in line with the reference product.**	
916.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 40mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 41963: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 40mg film-coated tablets. MHRA approved
	Me-too status	Rosugen Tablet 40mg. Reg. No. 84109
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Previous decision	The Board in tis 295th meeting deferred the case for for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised Rosuvastatin to Rosuvastatin (as calcium) in the label claim to without submission of fee.
	Decision: Deferred for fee for revision of salt form.	
917.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Thicoside Capsule 4mg
	Composition	Each capsule contains Thiocolchicoside……..…4mg
	Diary No. Date of R& I & fee	Dy. No 41964: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg capsule. ANSM approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved with innovator's specification.	
918.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Iron Fort Syrup
	Composition	Each 5ml contains Ferric Ammonium citrate …1000mg Folic Acid……..11mg Pyridoxine HCl.....……...48mg Thiamine HCl…….…..…...24mg Nicotinamide……..……220mg
	Diary No. Date of R& I & fee	Dy. No. 41965: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Iron with multi-Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200ml Bottle 1's As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	As above
	Remarks of the Evaluator(IX)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP. • Packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting not provided. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm not provided.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm**	
919.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cerin Capsule 50mg
	Composition	Each Capsule contains Diacerein……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 41966: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	ART 50 mg capsule. ANSM approved
	Me-too status	Diora 50mg Capsule. Reg. No. 67631
	GMP status	As above
	Remarks of the Evaluator(IX)	• Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.

	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved with innovator's specification.	
920.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ocedophine Tablet 400/60mg
	Composition	Each Tablet contains Ibuprofen……..……...400mg Pseudoephedrine HCl……60mg
	Diary No. Date of R& I & fee	Dy. No. 41967: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic Acid and sympathomimetics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lasynac Max Strength 400mg/60mg film coated tablets. MHRA Approved
	Me-too status	Irofen Forte Tablets. Reg. No. 42233
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised "Pseudoephedrine" to "Pseudoephedrine HCl" in composition. Revision of label claim is required along with submission of applicable fee. • Revision of formulation to film-coated tablet is required. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • The firm revised the tablet to film-coated tablet. • The firm revised "Pseudoephedrine" to "Pseudoephedrine HCl" in the label claim without submission of fee. • Revision of "Pseudoephedrine" to "Pseudoephedrine HCl" in master formula is still required.
	Decision: Deferred for: • **Fee for revision of salt form and formulation.** • **Revision of "Pseudoephedrine" to "Pseudoephedrine HCl" in master formula**	
921.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 100mg
	Composition	Each capsule contains Gabapentin……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 41968: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 100mg Capsules. MHRA approved
	Me-too status	Pentowan 100mg Capsule. Reg. No. 79688
	GMP status	As above
	Remarks of the Evaluator(IX)	Blistering and packing process is missing in the manufacturing outlines.

	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
922.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 300mg
	Composition	Each Capsule contains Gabapentin……..…300mg
	Diary No. Date of R& I & fee	Dy. No. 41969: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 300mg Capsules. MHRA approved
	Me-too status	Pentowan 300mg Capsule. Reg. No. 82103
	GMP status	As above
	Remarks of the Evaluator(IX)	Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
923.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 400mg
	Composition	Each Capsule contains Gabapentin……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 41970: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 400mg Capsules. MHRA approved
	Me-too status	NEURONTIN CAPSULES 400mg. Reg. No. 16141
	GMP status	As above
	Remarks of the Evaluator(IX)	Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines.
	Decision: Approved.	
924.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 200mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……200mg
	Diary No. Date of R& I & fee	Dy. No. 41971: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's As per SRO

	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 200 mg film-coated tablets MHRA Approved
	Me-too status	Haltrin 200mg Tablet. Reg. No. 61068
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
925.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 300mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……300mg
	Diary No. Date of R& I & fee	Dy. No. 41972: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 300 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 300mg Tablet. Reg. No. 58445
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
926.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 400mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 41973: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification

	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 400 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 400mg Tablet. Reg. No. 58446
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	The firm submitted revised manufacturing outlines. The firm revised the label claim to film-coated tablet without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
927.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Syrup 100mg.5ml
	Composition	Each 5ml contains Dexibuprofen ……100mg
	Diary No. Date of R& I & fee	Dy. No. 41974: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	120ml & 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Tercica 100mg/5ml. Reg. No. 61206
	GMP status	As above
	Remarks of the Evaluator(IX)	• Packing process is missing in the manufacturing outlines. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same formulation and same strength by DRAP.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting not provided.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

928.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ceral Tablet 6.4mg
	Composition	Each Film coated tablet contains Glyceryl Trinitrate……6.4mg
	Diary No. Date of R& I & fee	Dy. No. 41975: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Organic nitrates
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sustac 6.4mg prolonged release tablet. MHRA Approved
	Me-too status	Slotac S.Rtablet 6.4mg. Reg. No. 25168
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition to prolonged release tablet. Revision of label claim is required along with submission of applicable fee. • The firm revised glycerol to Glyceryl throughout the dossier. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Revision of label claim to prolonged release tablet is required along with submission of applicable fee.
	Decision: Deferred for revision of label claim to prolonged release tablet along with submission of applicable fee.	
929.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ceral Tablet 2.6mg
	Composition	Each Film coated tablet contains Glycerol Trinitrate……2.6mg
	Diary No. Date of R& I & fee	Dy. No. 41976: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Organic nitrates
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sustac 2.6mg prolonged release tablet. MHRA Approved
	Me-too status	Slotac S.Rtablet 6.4mg. Reg. No. 25167
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm revised the composition to prolonged release tablet. Revision of label claim is required along with submission of applicable fee. • The firm revised glycerol to Glyceryl throughout the dossier. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee.

		□ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Revision of label claim to prlonged release tablet is required along with submission of applicable fee.
	Decision: Deferred for revision of label claim to prolonged release tablet along with submission of applicable fee.	
930.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Soritic Tablet 20/12.5mg
	Composition	Each Tablet contains Lisinopril as dihydrate……...…20mg Hydrochlorothiazide……...12.5mg
	Diary No. Date of R& I & fee	Dy. No. 41978: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lisoretic 20 mg/12.5 mg Tablets, uncoated, MHRA approved
	Me-too status	Acinopril Plus Tablets. Reg. No. 76830
	GMP status	As above
	Remarks of the Evaluator(IX)	• Revise "Lisinopril dihydrate" to "Lisinopril as dihydrate" in the label claim. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • The firm revised "Lisinopril dihydrate" to "Lisinopril as dihydrate" in the label claim.
	Decision: Approved.	
931.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v Injection (0.5ml)
	Composition	Each 1ml contains Sodium Bicarbonate……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 41979: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	0.5ml Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (does not specify the pack volume)
	GMP status	As above
	Remarks of the Evaluator(IX)	• Provide evidence of approval of applied formulation (same filled volume) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

		• Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for following: □ Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. □ Submission of detailed method of sterilization.
	Evaluation by PEC	• The firm submitted revised manufacturing outlines. • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting	
932.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v Injection (1ml)
	Composition	Each 1ml contains Sodium bicarbonate……50mg
	Diary No. Date of R& I & fee	Dy. No. 41980: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	The product is present in 1ml pack size (50mg/ml) in combo pack of Artesunate injection. W.H.O. prequalified.
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (does not specify the pack volume)
	GMP status	As above
	Remarks of the Evaluator(IX)	Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for submission of detailed method of sterilization.
	Evaluation by PEC	□ The firm submitted revised manufacturing outlines.
	Decision: Approved.	
933.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/10 mg Tablet
	Composition	Each Tablet contains Ezetimibe……10mg Simvastatin……10mg
	Diary No. Date of R& I & fee	Form -5 Dy.No 41981: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	NeoCom –S Tablets. Reg. No. 42397
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following:

		□ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	□ The firm submitted revised manufacturing outlines. • The firm has mentioned coating composition and process in the revised manufacturing outlines. The international reference product is uncoated tablet.
	Decision: Deferred for revision of master formula and manufacturing outlines.	
934.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/20 mg Tablet
	Composition	Each Tablet contains Ezitimbe …….10mg Simvastatin……20mg
	Diary No. Date of R& I & fee	Dy. No. 41982: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	NeoCom –SD Tablets. Reg. No. 42398
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	□ The firm submitted revised manufacturing outlines. • The firm has mentioned coating composition and process in the revised manufacturing outlines. The international reference product is uncoated tablet.
	Decision: Deferred for revision of master formula and manufacturing outlines.	
935.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/40 mg Tablet
	Composition	Each Tablet contains Ezitimbe ……..…….10mg Simvastatin……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 42012: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved

	Me-too status	NeoCom –ST Tablets. Reg. No. 42399
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	□ The firm submitted revised manufacturing outlines. • The firm has mentioned coating composition and process in the revised manufacturing outlines. The international reference product is uncoated tablet.
	Decision: Deferred for revision of master formula and manufacturing outlines.	
936.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/80 mg Tablet
	Composition	Each Tablet contains Ezitimbe ……..….10mg Simvastatin……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 42013: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	Neutrachol Plus Tablets. Reg. No. 59304
	GMP status	As above
	Remarks of the Evaluator(IX)	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Previous decision	The Board in tis 295th meeting deferred the case for following: □ Revision of formulation as per reference product along with submission of requisite fee. □ Submission of complete outline of method of manufacturing.
	Evaluation by PEC	□ The firm submitted revised manufacturing outlines. • The firm has mentioned coating composition and process in the revised manufacturing outlines. The international reference product is uncoated tablet.
	Decision: Deferred for revision of master formula and manufacturing outlines.	
937.	**Deleted due to duplication**	
938.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	ROXAB 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……..2.5mg
	Diary No. Date of R& I & fee	Dy. No. 40703: 06.12.2018 Rs. 20,000/- : 06.12.2018

	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto Film Coated Tablet (2.5mg, 10mg, 15mg, 20mg). EMA approved
	Me-too status	XARELTO 2.5MG TABLETS. Reg. no. 74794
	GMP status	As above
	Remarks of the Evaluator(IX)	• Form 5 has been signed by the manager regulatory affairs. • The firm has changed the address in Form 5 from Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan to Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan without submission of any fee.
	Previous decision	The Board in tis 294th meeting deferred the case for clarification since the initial application was submitted by Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila which is a separate licensed manufacturer.
	Evaluation by PEC	This was a typographical mistake at the end of PEC. The cover letter endorsed by R&I and PEC are from the Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan. Form 5 bears the name of the same manufacturer. Moreover, the fee challan bear the DML No. 000782. The Board may examine the original file/dossier if it deems necessary.
	Decision: Approved.	
939.	**Name and address of manufacturer / Applicant**	**Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi**
	Brand Name +Dosage Form + Strength	Iborine Capsule 200mg
	Composition	Each capsule contains: Mebeverine HCl…….200mg
	Diary No. Date of R& I & fee	Dy No. 1735: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator(IX).	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same. • .
	Previous decision	The Board in its 289th meeting deferred the case for further deliberation.
	Evaluation by PEC	• The firm submitted that they use the testing method as specified by the manufacturer of the pellets.
	Previous decision	• The Board in its 291st meeting deferred the case for further deliberation

	Evaluation by PEC	• The firm again submitted that they use the testing method as specified by the manufacturer of the pellets.
	Previous decision	• The Board in its 295th meeting deferred the case for further deliberation
	Evaluation by PEC	• The firm requested for approval of the case as the case of M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore has already been approved.
	Decision: Approved with innovator's specifications.	
940.	**Name and address of manufacturer / Applicant**	**M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, Khyber Pakhtunkhwa**
	Brand Name +Dosage Form + Strength	Colomat 1 MIU Injection
	Composition	Each Vial Contains: Colistimethate Sodium (Lyophilized Powder)…1 MIU
	Diary No. Date of R& I & fee	Dy No. 25806: 26.07.2018 PKR 20,000/-: 26.07.2018
	Pharmacological Group	Polymyxins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	The firm was last inspected on 13.02.2018, wherein it was concluded that "Overall the firm was in good working condition with proper documentation, adequate Equipments both in production and quality control and qualified staff for performing the manufacturing and analysis of the manufactured products in accordance with the cGMP guidelines. Some of the minor shortcomings as described above were identified to the firm for immediate rectification. Based on the premises inspected, the qualified staff met and documentation reviewed, it is concluded that M/s Aulton Pharma Industrial Estate Hatter operate at good level of compliance with cGMP guidelines".
	Remarks of the Evaluator(IX).	Undertaking was not signed. The firm submitted duly signed form 5.
	Prevoius decision	The Board in its 291st meeting deferred the case for submission of undertaking.
	Evaluation by PEC	The firm has already submitted duly signed form 5
	Prevoius decision	The Board in its 293rd meeting deferred the case for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	The firm submitted cover letter wherein they have attached leaflet of some reference product, which does not clarify the reason behind the deferment of the case.
	Prevoius decision	The Board in its 295th meeting deferred the case for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	The firm submitted that the method of manufacturing is powder filling (lyophilized powder ready to fill). The firm submitted approval letter of dry powder injection (general).
	Decision: Approved.	
941.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K

	Brand Name + Dosage Form + Strength	Diltaia-alt 60mg Tablet
	Composition	Each Tablet Contains: Diltiazem Hydrchloride…60mg
	Diary No. Date of R & I & fee	Dy. No.39446; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DILTIAZEM HYDROCHLORIDE TABLETS 60mg uncoated prolonged release tablet. **MHRA** approved
	Me-too status	Myozem Tablets 60mg. Reg. No. 41982 (does not reveal prolonged release)
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator(IX)	• The reference product is uncoated prolonged release tablet. The firm has applied for film-coated tablet. The firm revised the formulation (label claim, composition) to uncoated (not prolonged release) tablet along with submission of applicable fee. Moreover, they have still mentioned film-coated tablet as dosage form.
	Prevoius decision	The Board in its 295th meeting deferred the case revision of formulation along with outline of method of manufacturing as per the reference product.
	Evaluation by PEC	The firm once again submitted Rs. 5000/- fee, but did not revise label claim and manufacturing outlines. The firm has mentioned Diltiazem instead of Diltiazem Hydrchloride in the master formula.
	Decision: Deferred for revision of label claim and correction of master formula.	
942.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Clomi Star 50mg Tablets
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R & I & fee	Dy. No.39447; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	GENRX CLOMIPHENE clomifene citrate 50mg tablet, un-coated. **TGA** approved
	Me-too status	OVA-MIT TABLETS. Reg. No. 20404
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator(IX)	• The reference product is uncoated tablet. The firm has applied for film-coated tablet. Upon clarification, the firm submitted Rs. 5000/- but did not revise the manufacturing outlines in line with the reference product. Moreover, they have still mentioned film-coated tablet as dosage form.
	Prevoius decision	The Board in its 295th meeting deferred the case revision of formulation along with outline of method of manufacturing as per the reference product.

	Evaluation by PEC	The firm submitted Rs. 5000/- fee, and revised the manufacturing outlines.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
943.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Aultafen 145mg Tablets
	Composition	Each Tablet Contains: Fenofibrate…145mg
	Diary No. Date of R & I & fee	Dy. No.39445; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Fibrates
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	FENOFIBRATE BIOGARAN 145 mg, comprimé uncoated. ANSM approved
	Me-too status	Fenoget 145mg Tablet. Reg. No. 58480
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator(IX)	• The reference product is uncoated tablet. The firm revised the formulation (label claim, composition) in line with the reference product along with submission of applicable fee. Moreover, they have still mentioned film-coated tablet as dosage form.
	Prevoius decision	The Board in its 295th meeting deferred the case for revision of formulation as per the reference product along with submission of fee for revision of formulation.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee, and revised the label the label claim, but did not revise the manufacturing outlines.
	Decision: Deferred for correction of manufacturing outlines.	
944.	**Name and address of manufacturer/Applicant**	**A. J. Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.**
	Brand Name+ Dosage Form+ Strength	**Glistat Tablet 4mg**
	Composition	Each tablet contains: Glimepiride…….. 4mg
	Dairy No. Date of R & I fee	Dy No. 7214: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 4 mg tablets, uncoated (MHRA Approved)
	Me-too status	Glimar Tablets 4mg. Reg. No. 75958
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator(IX)	The label claim was film-coated tablet, but coating composition and process are not mentioned in the application. The firm did not clarify the same.

	Previous decision	The Board in its 293rd meeting deferred the case for submission coating composition of the applied product and complete method of manufacturing with the detail of coating process.
	Evaluation by PEC	The firm submitted that the tablet is uncoated. It was a typo mistake in the label claim.
	Previous decision	The Board in its 295th meeting deferred the case for submission of requisite fee for revision of formulation.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee.
	Decision: Approved.	
945.	**Name and address of manufacturer/Applicant**	**A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.**
	Brand Name+ Dosage Form+ Strength	**Glistat Tablet 3mg**
	Composition	Each film-coated tablet contains: Glimepiride…….. 3mg
	Dairy No. Date of R & I fee	Dy No. 7213: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 3 mg tablets, uncoated (MHRA Approved)
	Me-too status	Evopride 3mg Tablet by M/s Pharmevo (Reg#29133)
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator(IX)	The label claim was film-coated tablet, but coating composition and process are not mentioned in the application. The firm did not clarify the same.
	Previous decision	The Board in its 293rd meeting deferred the case for submission coating composition of the applied product and complete method of manufacturing with the detail of coating process.
	Evaluation by PEC	The firm submitted that the tablet is uncoated. It was a typo mistake in the label claim.
	Previous decision	The Board in its 295th meeting deferred the case for submission of requisite fee for revision of formulation.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee.
	Decision: Approved.	
946.	**Name and address of manufacturer/Applicant**	**A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.**
	Brand Name+ Dosage Form+ Strength	**Zelotrine Tablet 5mg**
	Composition	Each film-coated tablet contains: Levocetirizine dihydrochloride…..5mg
	Dairy No. Date of R & I fee	Dy No. 7214: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL levocetirizine hydrochloride 5 mg film coated tablet blister pack. TGA approved
	Me-too status	Norzin 5 mg Tablets, film-coated. Reg. No. 77965
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).

	Remarks of the Evaluator(IX)	The firm was asked to revise 'Levoceterizine Dihydrochloride equivalent to Levoceterizine' to 'Levocetirizine Dihydrochloride' in the label claim and master formula. The firm neither revised the label claim nor revised the quantity of API to 5 mg in master formula.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The firm submitted that there is no need to change. • The firm needs to remove the equivalency in the label claim. • Regarding fee submission, the Registration Board is humbly requested to clarify the fee submission in case of pre-approval changes, as there is no written guidelines/rules for such fee. Cases of similar nature (adding or removing equivalency) have been approved without fee submission in various meetings.
	Previous decision	The Board in its 295th meeting deferred the case for of label claim and master formulation along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	The firm revised the master formulation and submitted Rs. 5000/- fee.
	Decision: Approved.	
947.	**Name and address of manufacturer/Applicant**	**A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.**
	Brand Name+ Dosage Form+ Strength	**Zelotrine 2.5mg/5ml Syrup**
	Composition	Each 5ml contains: Levocetirizine Dihydrochloride…..2.5mg
	Dairy No. Date of R & I fee	Dy No. 7202: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	60ml amber coloured bottle , As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL (levocetirizine dihydrochloride) oral solution 0.5mg/ml. USFDA approved
	Me-too status	T-Day Syrup 2.5mg/5ml. Reg. No. 83990
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator(IX)	The firm was asked to revise 'Levoceterizine Dihydrochloride equivalent to Levoceterizine' to 'Levocetirizine Dihydrochloride' in the label claim and master formula. The firm neither revised the label claim nor revised the quantity of API to 5 mg in master formula.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The firm submitted that there is no need to change. • The firm needs to remove the equivalency in the label claim. • Regarding fee submission, the Registration Board is humbly requested to clarify the fee submission in case of pre-approval changes, as there is no written guidelines/rules for such fee. Cases of similar nature

		have been approved without fee submission in various meetings.
	Previous decision	The Board in its 295th meeting deferred the case for of label claim and master formulation along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	The firm revised the master formulation and submitted Rs. 5000/- fee.
	Decision : Approved with innovator's specification.	
948.	**Name and address of manufacturer / Applicant**	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Fleet Plus 75/75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel as bisulphate……75mg Aspirin……..75mg
	Diary No. Date of R& I & fee	Dy. No. 40691: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	APO-CLOPIDOGREL/ASPIRIN 75 mg / 75 mg film-coated tablets. TGA approved
	Me-too status	Lowplat Plus 75 Tablet. Reg. no. 47177
	GMP status	OKK
	Remarks of the Evaluator(IX)	• Form 5 has been signed by the manager regulatory affairs. • The firm has mentioned clopidogrel as bilsulfate in the cover letter, but the dossier does not depict the same elsewhere. Upon clarification the firm revised clopidogrel to clopidogrel as bisulfate without submission of any fee.
	Previous decision	The Board in its 295th meeting deferred the case for following: □ Submission of fee for revision / correction of salt form of the API. □ Submission of revised manufacturing method in line with that of the reference product.
	Evaluation by PEC	The firm revised the aspirin to pellets of aspirin and submitted RS. 5000/- fee.
	Decision: Deferred for: • **Submission of fee for revision / correction of salt form of the API.** • **Clarification regarding revision of the aspirin to pellets of aspirin** • **Clarification regarding the formulation, bilayer or otherwise.**	
949.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RAFAZIN Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Rifaximin…….200mg
	Diary No. Date of R& I & fee	Dy. No. 40681: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 200mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nimixa 200mg Tablet film-coated. Reg. No. 70734
	GMP status	AS ABOVE
	Remarks of the Evaluator(IX)	• Form 5 has been signed by the manager regulatory affairs.

		• The manufacturing outlines were meant for cream. The firm revised the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for submission of manufacturing method of the applied product.
	Evaluation by PEC	The firm has already revised the manufacturing outlines.
	Decision: Approved.	
950.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RAFAZIN Tablet 550mg
	Composition	Each Film Coated Tablet Contains: Rifaximin…….550mg
	Diary No. Date of R& I & fee	Dy. No. 39682: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Antibotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 550mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nim[IX]a 550mg Tablet film-coated. Reg. No. 70733
	GMP status	AS ABOVE
	Remarks of the Evaluator[(IX)]	• Form 5 has been signed by the manager regulatory affairs. • The manufacturing outlines were meant for cream. The firm revised the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for submission of manufacturing method of the applied product.
	Evaluation by PEC	The firm has already revised the manufacturing outlines.
	Decision: Approved.	
951.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	TUKOL CR 25mg Tablet
	Composition	Each Enteric Coated Controlled Release Tablet Contains: Paroxetine as HCl hemihydrate……25mg
	Diary No. Date of R& I & fee	Dy. No. 40487: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR (paroxetine) extended-release tablets, enteric coated (12.5mg, 25mg, 37.5mg). USFDA approved
	Me-too status	Approved
	GMP status	AS ABOVE
	Remarks of the Evaluator[(IX)]	• Form 5 has been signed by the manager regulatory affairs • The firm did not mention seal coating and enteric coating separately in the master formula as well as manufacturing outlines. • The firm revised the formulation to Enteric Coated Controlled Release Tablet without submission of fee.
	Previous decision	The Board in its 295th meeting deferred the case for • Submission of fee for revision of formulation. • Submission of revised master formulation and manufacturing method in line with that of the reference product.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee, but did not clarify the manufacturing process and composition. Moreover, Paroxetine

		as HCl hemihydrate shall be mentioned instead of Paroxetine as HCl.
	Decision: Deferred for: • **Clarification of the manufacturing process and composition.** • **Revision of Paroxetine as HCl to Paroxetine as HCl hemihydrate**	
952.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LYSINE 300mg Capsule
	Composition	Each Capsule Contains: 408mg of Lymecycline Equivalent to 300mg Tetracycline Base (BP Specifications)
	Diary No. Date of R& I & fee	Dy. No. 42053: 07.12.2018 Rs. 20,000/- : 07.12.2018
	Pharmacological Group	Tetracyclines
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 14's, 20's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Tetralysal 300 mg Hard Capsules. MHRA Approved
	Me-too status	Macyline Capsule 300mg. Reg. No.
	GMP status	AS ABOVE
	Remarks of the Evaluator(IX)	Form 5 has been signed by the manager regulatory affairs
	Previous decision	The Board in its 295th meeting deferred the case for confirmation of label claim.
	Evaluation by PEC	The firm submitted references having same label claim as applied.
	Decision: Approved	
953.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi contract manufacturing by: M/s Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Stazz Injection 250mg IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IV) by Lupin Pharmaceuticals Inc. **US-FDA** approved
	Me-too status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator(IX).	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.

		• Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing • That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved.	
954.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi contract manufacturing by: M/s Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Stazz Injection 500mg IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IV). US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV. Reg. No. 78097
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator(IX).	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.

		• Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing • That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved.	
955.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi**
	Brand Name +Dosage Form + Strength	Stazz Injection 1g IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1g
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 1 g (IV). US-FDA approved
	Me-too status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection. Reg. No. 70663
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator(IX).	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing

		• That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved	
956.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi contract manufacturing by: M/s Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Getfix 100mg/5ml dry suspension
	Composition	Each 5ml contain: Cefixime as trihydrate……100mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator[IX].	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing • That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved.	
957.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi contract manufacturing by: M/s Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi**

	Brand Name +Dosage Form + Strength	Getfix 200mg/5ml dry suspension
	Composition	Each 5ml contain: Cefixime as trihydrate……200mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator(IX).	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing • That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved.	
958.	**Name and address of manufacturer / Applicant**	**Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi contract manufacturing by: M/s Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151, Sector 24 Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Getfix Capsule 400mg
	Composition	Each capsule contain: Cefixime as trihydrate……400mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins

	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules, for oral use by Lupin Ltd for Lupin Pharma. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule by Nawan Lab. Karachi. Reg. No. 82219
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator(IX).	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Previous decision	The Board in its 292nd meeting deferred the case for: • Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Evaluation by PEC	The firm submitted: • Contract manufacturing agreement • That they have not applied for contract manufacturing • That products have not registered for contract manufacturing • List of 05 approved sections
	Decision: Approved.	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

b. New/Additional section(s)

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

b. Deferred Cases

959.	**Name and address of manufacturer/ Applicant**	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.**
	Brand Name + Dosage Form + Strength	Solomox Powder
	Composition	Each 100g contains: Amoxicillin as Trihydrate…70gm
	Diary No. Date of R & I & fee	Dy. No. 32756; 02.10.2018 PKR. 20,000/-; 02.10.2018

	Pharmacological Group	Penicillins with extended spectrum
	Type of Form	Form 5
	Finished product Specification	USP (for suspension, which shall contain one or more suitable buffers, colors, flavors, preservatives, stabilizers, sweeteners and suspending agents).
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg; Decontrolled
	Me-too status	Primox 70% Water Soluble Powder. Reg. No. 74032
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator(IX)	• The USP monograph has specified that for suspension shall contain one or more suitable buffers, colors, flavors, preservatives, stabilizers, sweeteners and suspending agents). The product does not contain such agents.
	Previous decision	The Board in its 293rd meeting deferred the case for clarification of difference in composition of the applied formulation and the composition described in individual monograph of the product (USP).
	Evaluation by PEC	The firm submitted that they have applied for product with BP specifications.
	Decision: approved with BP specifications.	
960.	**Name and address of manufacturer / Applicant**	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore**
	Brand Name +Dosage Form + Strength	Trypnil Granules for Injection
	Composition	Each 2.36gm Sachet contains: Diminazene Diaceturate…1.05g
	Diary No. Date of R& I & fee	Dy No. 22520: 28.06.2018 PKR 20,000/-: 28.06.2018
	Pharmacological Group	Trypanocidal agent (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2.36g sachet; Decontrolled
	Me-too status	NAGANIL POWDER (**Sachet**). Reg. No. 26516
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended.
	Remarks of the Evaluator(IX).	•
	Previous decision	The Board in its 291st meeting deferred the case for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	The firm submitted that they shall be granted registration in vial, as vial is more suitable than scahet: • Any variation (color or particles) of the contents of filled power in sachet is not visible and the other hand is easily visible in vial. • Volume after reconstitution is easily measurable in vial rather than sachet. • Sterility of product not possible in sachet. • Particles not seen after reconstitution in sachet but visible in vial. • Optical checking not possible in sachet.
	Decision: Referred to working group on veterinary drugs.	
961.	**Name and address of manufacturer / Applicant**	**M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad** **By** **M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	F-Zix 400mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Cefixime as Trihydrate…400mg
	Diary No. Date of R& I & fee	Dy No. 30421: 10.09.2018 PKR 50,000/-: 10.09.2018

	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	1x5's; as per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules, for oral. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule. Reg. No. 82219
	GMP status	Applicant: The firm was last inspected on 18.01.2018, wherein the panel recommended the renewal of DML no. 000610 by way of formulation. Manufacturer: The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP complaint.
	Remarks of the Evaluator(IX).	• The firm M/s Fresh Pharmaceuticals did not submit list of approved sections of M/s Fresh Pharmaceuticals. • The firm M/s Fresh Pharmaceuticals did not submit list of approved product for contract manufacturing. • The firm M/s Fresh Pharmaceuticals submitted list of 03 applied products for contract manufacturing.
	Previous decision	The Board in its 293rd meeting deferred for the following: • Submission of list of approved sections of M/s Fresh Pharmaceuticals. • Submission list of approved products for contract manufacturing.
	Evaluation by PEC	• The firm submitted that they have no applied or registered product for contract manufacturing and submitted list of 05 sections.
	Decision: Approved.	
962.	**Name and address of manufacturer / Applicant**	**M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad** **By** **M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	F-Zix 100mg/5ml Dry Suspension
	Composition	Each 5ml of reconstituted Suspension Contains: Cefixime as Trihydrate…100mg
	Diary No. Date of R& I & fee	Dy No. 30419: 10.09.2018 PKR 50,000/-: 10.09.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	Applicant: The firm was last inspected on 18.01.2018, wherein the panel recommended the renewal of DML no. 000610 by way of formulation. Manufacturer: The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP complaint.
	Remarks of the Evaluator(IX).	• The firm M/s Fresh Pharmaceuticals did not submit list of approved sections of M/s Fresh Pharmaceuticals. • The firm M/s Fresh Pharmaceuticals did not submit list of approved product for contract manufacturing. • The firm M/s Fresh Pharmaceuticals submitted list of 03 applied products for contract manufacturing.
	Previous decision	The Board in its 293rd meeting deferred for the following:

		• Submission of list of approved sections of M/s Fresh Pharmaceuticals. • Submission list of approved products for contract manufacturing.
	Evaluation by PEC	• The firm submitted that they have no applied or registered product for contract manufacturing and submitted list of 05 sections.
	Decision: Approved.	
963.	**Name and address of manufacturer / Applicant**	**M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad** **By** **M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	F-Zix 200mg/5ml Dry Suspension
	Composition	Each 5ml of reconstituted Suspension Contains: Cefixime as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy No. 30420: 10.09.2018 PKR 50,000/-: 10.09.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	Applicant: The firm was last inspected on 18.01.2018, wherein the panel recommended the renewal of DML no. 000610 by way of formulation. Manufacturer: The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP complaint.
	Remarks of the Evaluator(IX).	• The firm M/s Fresh Pharmaceuticals did not submit list of approved sections of M/s Fresh Pharmaceuticals. • The firm M/s Fresh Pharmaceuticals did not submit list of approved product for contract manufacturing. • The firm M/s Fresh Pharmaceuticals submitted list of 03 applied products for contract manufacturing.
	Previous decision	The Board in its 293rd meeting deferred for the following: • Submission of list of approved sections of M/s Fresh Pharmaceuticals. • Submission list of approved products for contract manufacturing.
	Evaluation by PEC	• The firm submitted that they have no applied or registered product for contract manufacturing and submitted list of 05 sections.
	Decision: Approved.	
964.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Tri-Pen LA Injection
	Composition	Each ml contains: Benzathine Pencillin G…..…….100,000 IU Procaine Penicillin G……..150,000 IU Dihydrostreptomycin as sulphate……..200 mg
	Diary No. Date of R&I & Fee	Dy. No. 21204: 18-10-2019, Rs. 20,000/-: 18-10.2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	BPS-LA Injection (50ml). Reg. 080951

	GMP status	New Section Veterinary Liquid Injection Penicillin
	Remarks of the Evaluator(IX)	• Revise "Dihydrostreptomycin sulphate" to "Dihydrostreptomycin as sulphate" in the label claim only and adjust the weight of Dihydrostreptomycin sulphate in Master formula as per salt factor.
	Previous decision	The Board in its 294th meeting deferred the case revision of formulation including the salt form as per the DRAP approved generic product along with submission of revised master formulation and requisite fee.
	Evaluation by PEC	The frim submitted Rs. 5000/- fee. However, they did not revise "Dihydrostreptomycin sulphate" to "Dihydrostreptomycin as sulphate" in the label claim. In previous cases, the Board did not demand fee for revision of API in terms of salt equivalency.
	Previous decision	The Board in its 295th meeting deferred the case for revision of formulation as per the me-too product.
	Evaluation by PEC	The firm revised Dihydrostreptomycin sulphate to Dihydrostreptomycin as sulphate in the label claim.
	Decision: approved with innovator's specifications.	
965.	**Name and address of manufacturer/ Applicant**	**M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan**
	Brand Name + Dosage Form + Strength	Easehale 0.025% Respules 1ml
	Composition	Each 1ml Contains: Ipratropium bromide as monohydrate…0.025%
	Diary No. Date of R & I & fee	Dy. No. 30195; 07.09.2018 PKR. 20,000/-; 07.09.2018
	Pharmacological Group	Anticholinergics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	5'sx1ml (Polyethylene); As per SRO
	Approval status of product in Reference Regulatory Authorities	AERON 250 ipratropium bromide anhydrous 250 microgram/mL inhalation ampoule (LDPE). TGA approved, wherein active is ipratropium bromide monohydrate 261 microgram/mL. IPRATRIN UNI-DOSE ipratropium bromide monohydrate 250microgram/1mL inhalation ampoule. TGA approved
	Me-too status	Optra Nebuliser Solution. Reg. No. 57885
	GMP status	The firm was inspected on 03.04.2019, wherein **acceptable level** of GMP compliance was reported.
	Remarks of the Evaluator(IX)	• The firm was asked to revise label claim to "Ipratropium bromide as monohydrate. The firm did not revise the same.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of label claim to Ipratropium bromide as monohydrate as per the label claim of the reference product.
	Evaluation by PEC	• The firm revised the label claim to Ipratropium bromide as monohydrate.
	Previous decision	The Board in its 295th meeting deferred the case for submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The Board may review its decision.
	Decision: Approved.	
966.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Super TD Powder 20/25g
	Composition	Each 100 gram contains: Tylosin Tartrate…20g Doxycycline hyclate…25g
	Diary No. D of R & I & Fee	Dy.No 1160: 09-01-2019 Rs. 20,000/-: 04-01-2019
	Pharmacological group	Antibiotics

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	RAPID-TD WATER SOLUBLE POWDER (20%/25%). Reg. No. 75660
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • The firm had mentioned "Each gram contains: Tylosin Tartrate…20g, Doxycycline hyclate…25g in the label claim and Tylosin Tartrate…200g, Doxycycline HCl…250g per kg in master formula. Upon clarification, the firm revised the label claim to "Each 100 gram contains: Tylosin Tartrate…20g, Doxycycline hyclate…25g" without submission of fee. • Revision of Doxycycline HCl to Doxycycline hyclate in master formula is required.
	Previous decision	The Board in its 295th meeting deferred the case for revision of formulation alongwith applicable fee.
	Evaluation by PEC:	The firm revised Doxycycline HCl to Doxycycline hyclate in master formula
	Decision: Approved.	
967.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	V-Mox LA 15 % Injection
	Composition	Each ml contains: Amoxicillin as trihydrate……..150 mg
	Diary No. Date of R & I & fee	Dy. No. 42889; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Penicillins
	Types of Form	Form-5
	Finished Product Specification	In-house specifications. The product is available in USP as powder for injectable suspension.
	Pack Size & Demanded Price	10 ml Decontrolled
	Me-too status	Symox LA Injection (10ml, 50ml, 100ml). Reg. No. 058999
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator[IX]	
	Previous decision	The Board in its 295th meeting deferred the case for clarification whether product is long acting (as mentioned in brand name) or otherwise (as no long acting claim in brand name) and confirmation of section.
	Evaluation by PEC:	The firm submitted letter of approval of sterile liquid injectable penicillin (vet) section and submitted that the product is long acting.
	Decision: Deferred for further deliberation regarding composition of long acting formulation.	
968.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Imivetz Injection
	Composition	Each ml contains: Imidocarb dipropionate……120 mg
	Diary No. Date of R & I & fee	Dy. No. 42891; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Antiprotozoal agent
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	10 ml Decontrolled
	Me-too status	Impisal Injection (10ml, 20ml, 30ml, 100ml). Reg. No. 063590

	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator[IX]	Terminal sterilization is missing in the manufacturing outlines. Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP.
	Previous decision	The Board in its 295th meeting deferred the case for: • Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Approved with innovator's specifications.	
969.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vitaflox 20 % Injection
	Composition	Each ml contains: Enrofloxacin ……..…..…..200 mg
	Diary No. Date of R & I & fee	Dy. No. 42889; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Fluoroquinolone
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 ml Decontrolled
	Me-too status	Enflox 20 % Injection (50ml, 100ml). Reg. no. 048153
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator[IX]	Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines.
	Decision: Approved with innovator's specifications.	
970.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vetzphos Injection
	Composition	Each ml contains: Sodium acid phosphate…….…400 mg
	Diary No. Date of R & I & fee	Dy. No. 43742; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Phosphate deficiency (general tonic)
	Types of Form	Form-5
	Finished Product Specification	In-house specifications. Avaialable in USP as (Each mL contains: Monobasic sodium phosphate, monohydrate, 276 mg; dibasic sodium phosphate, anhydrous, 142 mg (equivalent to dibasic sodium phosphate, heptahydrate, 268 mg); Water for Injection q.s. In the 5 mL and 15 mL product, phosphoric acid and/or NaOH may have been added for pH adjustment.)
	Pack Size & Demanded Price	250 ml Decontrolled
	Me-too status	Alphos-40 Injection (10ml, 20ml, 50ml, 100ml). Reg. No. 046573

	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator[IX]	Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP. Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	• The Board in its 295th meeting deferred the case for justification and evidence of applied pack size.
	Evaluation by PEC:	The firm submitted the following dosage: • Cattle / buffalo / horses: 200-250ml (IV single use for 250 ml) • Sheep goat: 50-70ml • Dogs/ cats: 10-20ml • Camels: 300-350ml Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
971.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+Strength	Veticam Plus Injectin
	Composition	Each ml contains: Meloxicam……..…..20 mg
	Diary No. Date of R & I & fee	Dy. No. 42888; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	50ml; Decontrolled
	Me-too status	Metrym Injection (50ml, 100ml). Reg. no. 044961
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator[IX]	Terminal sterilization/ sterile filling process is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines.
	Decision: Approved with innovator's specification.	
972.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Aceclovetz Injection
	Composition	Each ml contains: Aceclofenac……. 25 mg
	Diary No. Date of R & I & fee	Dy. No. 42887; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Acetic acid derivatives and related substances
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	50 ml Decontrolled
	Me-too status	Aceclovetz Injection (50ml). Reg. No. 084970 By same firm
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.

	Remark of Evaluator	Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP. Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for: • Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines. • The firm submitted me-too of Selmore Pharma, which is registered as EACH ML CONTAINS: ACECLOFENAC SODIUM EQ. TO ACECLOFENAC.....25MG (50ml). However, the label has aceclofenac (base)
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
973.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Aminovetz injection 500ml
	Composition	Each ml contains Dextrose …….50 mg Calcium chloride …….0.15mg Potassium chloride……. 0.2mg Magnesium Sulfate…….. 0.2mg Sodium acetate trihydrate ……2.5mg L-Histidine HCl …..……..0.34mg DL-Methionine ……0.34mg DL-Tryptophan ……0.34mg L-Cysteine HCl ……0.34mg L-Threonine ……0.68mg DL-Isoleucine ……0.68mg L-Arginine HCl ……0.85mg DL-Phenylalanine …….1.02mg DL-Valine ……..1.7mg L-Lysin HCl ……..1.02mg L-Leucine …….1.36mg Monosodium glutamate ……1.36mg Vitamin B1 (Thiamin HCl) …….0.10mg Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……..1.5mg
	Diary No. Date of R & I & fee	Dy. No. 42892; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Amino Acid/ Electrolytes/ Vitamins
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	500 ml Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remark of Evaluator	The composition do not match with the provided me-too. Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for:

		• Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines. • The revise the composition as follow along with submission of Rs. 20000/- dated 18.08.2020	
		Each ml contains Dextrose ……50 mg Calcium chloride ……0.15mg Potassium chloride…… 0.2mg Magnesium Sulfate…… 0.2mg Sodium acetate trihydrate …2.5mg L-Histidine HCl …..…0.34mg DL-Methionine ……0.34mg DL-Tryptophan ……0.34mg L-Cysteine HCl ……0.34mg L-Threonine ……0.68mg DL-Isoleucine ……0.68mg L-Arginine HCl ……0.85mg DL-Phenylalanine ……1.02mg DL-Valine ……1.7mg L-Lysin HCl ……1.02mg L-Leucine ……1.36mg Monosodium glutamate …1.36mg Vitamin B1 (Thiamin HCl) …0.10mg Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……1.5mg	Each 100ml contains Dextrose …….5.5 mg Calcium chloride ……15mg Potassium chloride…… 20mg Magnesium Sulfate…… 20mg Sodium acetate trihydrate ……250mg L-Histidine HCl …..……34mg DL-Methionine ……34mg DL-Tryptophan ……34mg L-Cysteine HCl ……34mg L-Threonine ……68mg DL-Isoleucine ……68mg L-Arginine HCl ……85mg DL-Phenylalanine ……102mg DL-Valine ……170mg L-Lysin HCl ……102mg L-Leucine ……136mg Monosodium glutamate ……136mg Vitamin B1 (Thiamin HCl) …10mg Vitamin B2 (Riboflavin-5-Phosphate).. 4mg Vitamin B6 (Pyridoxine Hydrochloride)..10mg Vitamin B12 (Cyanocobalamin) …..5mcg Nicotinamide ……150mg Benzyl alcohol…1.5mg Sterile water QS…100ml
		The firm submitted the following me-too product, the composition of varies from our me-too database.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.		
974.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh	
	Brand Name +DosageForm+Strength	Aminovetz injection 250ml	
	Composition	Each ml contains Dextrose ……50 mg Calcium chloride ……0.15mg Potassium chloride…… 0.2mg Magnesium Sulfate…….. 0.2mg Sodium acetate trihydrate ……2.5mg L-Histidine HCl …..……..0.34mg DL-Methionine ……0.34mg DL-Tryptophan ……0.34mg L-Cysteine HCl ……0.34mg L-Threonine ……0.68mg	

		DL-Isoleucine ……0.68mg L-Arginine HCl ……0.85mg DL-Phenylalanine ……1.02mg DL-Valine ……..1.7mg L-Lysin HCl ……..1.02mg L-Leucine ……1.36mg Monosodium glutamate ……1.36mg Vitamin B1 (Thiamin HCl) ……0.10mg Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……..1.5mg
	Diary No. Date of R & I & fee	Dy. No. 42896; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Amino Acid/ Electrolytes/ Vitamins
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	250 ml Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remark of Evaluator	The composition do not match with the provided me-too. Terminal sterilization is missing in the manufacturing outlines.
	Previous decision	The Board in its 295th meeting deferred the case for: • Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC:	• The firm submitted revised manufacturing outlines. • The revise the composition as follow along with submission of Rs. 20000/- dated 18.08.2020

Each ml contains	Each 100ml contains
Dextrose ……50 mg	Dextrose …….5.5 mg
Calcium chloride ……0.15mg	Calcium chloride ……15mg
Potassium chloride…… 0.2mg	Potassium chloride…… 20mg
Magnesium Sulfate…… 0.2mg	Magnesium Sulfate…… 20
Sodium acetate trihydrate …2.5mg	Sodium acetate trihydrate ……250mg
L-Histidine HCl …..…0.34mg	L-Histidine HCl …..……34m
DL-Methionine ……0.34mg	DL-Methionine ……34r
DL-Tryptophan ……0.34mg	DL-Tryptophan ……34mg
L-Cysteine HCl ……0.34mg	L-Cysteine HCl ……34mg
L-Threonine ……0.68mg	L-Threonine ……68mg
DL-Isoleucine ……0.68mg	DL-Isoleucine ……68m
L-Arginine HCl ……0.85mg	L-Arginine HCl ……85mg
DL-Phenylalanine ……1.02mg	DL-Phenylalanine ……102
DL-Valine ……1.7mg	DL-Valine ……170mg
L-Lysin HCl ……1.02mg	L-Lysin HCl ……102mg
L-Leucine ……1.36mg	L-Leucine ……136mg
Monosodium glutamate …1.36mg	Monosodium glutamate ……136mg
Vitamin B1 (Thiamin HCl) …0.10mg	Vitamin B1 (Thiamin HCl) …10mg
Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg	

			Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……1.5mg	Vitamin B2 (Riboflavin-5-Phosphate).. 4mg Vitamin B6 (Pyridoxine Hydrochloride)..10mg Vitamin B12 (Cyanocobalamin) …..5mcg Nicotinamide ……150mg Benzyl alcohol…1.5mg Sterile water QS…100ml
			The firm submitted the following me-too product, the composition of varies from our me-too database.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.			

Case no. 06 Registration applications of import cases

a. New Cases (Human)

b. New Cases (Veterinary)

c. Deferred cases

i. Human

ii. Veterinary

975.	**Name and address of Applicant**	**M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan**
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by **Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim.**

		• Legalized copy of GMP certificate issued by **Department of Animal Health of Vietnam for five years from 23.1.2017.** • Letter of authorization is provided.
	Remarks of the Evaluator(IX).	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • **Only brand name has been mentioned without label claim.** • The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis. • Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA. • The firm submitted Legalized copy of FSC issued by **Department of Animal Health of Vietnam valid for two years from 26.09.2019.**
	Previous decision	The Board in its 293rd meeting deferred the case for changing the address of applicant in form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Previous decision	• The Board in its 293rd meeting deferred the case for: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The me-too staus had already been mentioned as above. Another me-too is: DOXYSIN WATER SOLUBLE POWDER. Reg. No. 33256
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

Evaluator-PEC-VII

Item No. I: Cases Related to Covid-19 Management.

Drug Regulatory Authority of Pakistan in its 85th meeting held on 09th June, 2020 discussed Favipiravir

use in COVID-19 management by countries like China, Russia & Saudi Arabia and further its approval in Japan as antiviral against influenza viruses. Keeping in view the current outbreak of COVID-19, the Authority allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5F for registration of Favipiravir.

The Authority in the said meeting advised Director (PE&R) to consider the applied registration applications of Favipiravir in the ongoing meeting without waiting for the formal minutes of the Authority.

1. The applicants can submit their applications till 31-07-2020 and these applications will be considered out of queue.
2. Registration Board shall consider grant of registration under proviso of Rules 29(6) (8) of the Drug (Licensing, Registration & Advertising) Rules, 1976 and shall follow precautions / terms & conditions as adopted by the Reference Regulatory Authorities.
3. The registration holders including those granted registration under Form 5D as a new drug will submit data of product development and 6 months accelerated and 6 months real time stability studies data within one year alongwith other data as may be required by Registration Board. The data will be considered by Registration Board for further decision.

Keeping in view the above decision and directions of the Authority; the Board considered following applications of Favipiravir and decided as mentioned against each:

1. Favipiravir Tablet 200mg:

Composition

Each Film coated tablet contains:

Favipiravir…….200mg

Availability in RRA: Avigan 200mg Film coated Tablet by M/s Toyama Chemical Co., Ltd Japan (PMDA Approved)

Me too status: Not confirmed

Pharmacological group: Antiviral

Specifications: Innovator"s specifications

S. No.	Name of applicant	Brand Name	composition	Diary no. Date /Fee & Date/ form	Pack size/ Price	Remarks/GMP status	Decision
976.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Aviwan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 13477 dated 11/06/2020 Rs. 50,000/- dated 11-06-2020 (#2037902) Form 5D	As per SRO	Good compliance of GMP, inspection date 26/12/2019.	**Approved with innovator's specification.**
977.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Covigon 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 13954 dated 17/06/2020 Rs. 50,000/- dated 17-06-2020 (#2037453) Form 5D	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.	**Approved with innovator's specification.**
978.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	Safvir 200mg tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 13660 dated 15/06/2020 Rs. 50,000/- dated 15-06-2020 (#0228324) Form 5D	As per SRO	Last GMP inspection conducted on 08-10-2019, and the report concludes that the firm is considered to be operating at	**Approved with innovator's specification.**

						Good level of compliance with GMP guidelines	
979.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Favip 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 13663 dated 15/06/2020 Rs. 50,000/- dated 15-06-2020 (#2030754) Form 5D	14's. 28's As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.	**Approved with innovator's specification.**
980.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Favigan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14132 dated 18/06/2020 Rs. 50,000/- dated 18-06-2020 (#2031388) Form 5D	14's. 28's As per SRO	25-9-2019 Panel recommended the renewal of DML	**Approved with innovator's specification.**
981.	M/s Neutro Pharmaceuticals Pvt Ltd. 9.5-km sheikhupura Road, Lahore, Pakistan	Favip 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14519 dated 23/06/2020 Rs. 50,000/- dated 23-06-2020 Form 5D	As per SRO	GMP certificate issued on 11-07-2019 on the basis of inspection conducted on 28/02/2019	**Approved with innovator's specification.**
982.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Xovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 13957 dated 17/06/2020 Rs. 20,000/- dated 17-06-2020 (#2031650) Form 5	10's. 20's 30's As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
983.	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Frovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 13952 dated 17/06/2020 Rs. 50,000/- dated 17-06-2020 (# 2041711) Form 5D	As per SR	The firm was operating at good level of compliance with GMP as per inspection report dated 06/12/2018.	**Approved with innovator's specification.**
984.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Fast 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 13775 dated 16/06/2020 Rs. 50,000/- dated 16-06-2020 (#2042103) Form 5D	As per SRO	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019	**Approved with innovator's specification.**

985.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Farivir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 13771 dated 16/06/2020 Rs. 50,000/- dated 16-06-2020 (#2040652) Form 5D	10's. 30's, 100 's As per SRO	Last inspection dated 05-08-2019 concluded acceptable level of GMP compliance	**Approved with innovator's specification.**
986.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK	Fapavir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14224 dated 19/06/2020 Rs. 50,000/- dated 19-06-2020 (#2037883) Form 5D	As per SRO	The firm was inspected on 12/05/18 concluding Good level of cGMP.	**Approved with innovator's specification.**
987.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan	Favimac 200mg tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 14225 dated 19/06/2020 Rs. 50,000/- dated 19-06-2020 (#2027121) Form 5D	14's. 28's As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.	**Approved with innovator's specification.**
988.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Fapa-v 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14517 dated 23/06/2020 Rs. 50,000/- dated 23-06-2020 (#2027682) Form 5D	As per SRO	GMP certificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2018.	**Approved with innovator's specification.**
989.	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Favibar 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 14851 dated 25/06/2020 Rs. 50,000/- dated 25-06-2020 (#2027714) Form 5D	10's. 20's 30's. 40's As per SRO	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.	**Approved with innovator's specification.**

990.	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad	Virag 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14849 dated 25/06/2020 Rs. 50,000/- dated 25-06-2020 (#0806415) Form 5D	10's 30's. As per SRO	Last GMP inspection was conducted on 07-12-2017 Conclusion: M/s Magns Pharmaceuticals Faisalabad was considered to be operating at good level of compliance with GMP compliance of the firm.	**Approved with innovator's specification.**
991.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan	Jp-Favor 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14850 dated 25/06/2020 Rs. 20,000/- dated 24-06-2020 (#2000257) + 30,000/- dated 15-7-2020 (#2046466) Form 5D	As per SRO	The panel recommended renewal of DML, inspection date 03/05/2019.	**Approved with innovator's specification.**
992.	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Favink 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 14247 dated 24/06/2020 Rs. 20,000/- dated 22-06-2020 (#2048488) Form 5	As per SRO	Last GMP inspection conducted on 20-12-2017 and report concludes that the panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest." (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

993.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Vicor 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14741 dated 24/06/2020 Rs. 50,000/- dated 24-06-2020 (#2041345) Form 5D	10's. 20's 30's. 40's 50's. 100's As per SRO	Last GMP inspection dated 5th & 27th December conclusion by Panel "The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection"	**Approved with innovator's specification.**
994.	M/s Hamaz Pharmaceuticals Pvt Ltd. Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan	Hamivir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14744 dated 24/06/2020 Rs. 50,000/- dated 24-06-2020 (#2048952) Form 5	As per SRO	GMP certificate issued on 06/11/2019.	**Approved with innovator's specification.**
995.	M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad	Favira or Antvir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 14515 dated 23/06/2020 Rs. 50,000/- dated 23-06-2020 (#0748300) Form 5D	14's. 28's As per SRO	Last inspection dated 19-7-2017 recommends grant of DML	**Approved with innovator's specification.**
996.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan	Fabivir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14354 dated 22/06/2020 Rs. 50,000/- dated 22-06-2020 (#2032561) Form 5D	As per SRO	Last GMP inspection was conducted on 12-07-2019 and the report concludes good level of GMP compliance.	**Approved with innovator's specification.**
997.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Copravir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15046 dated 26/06/2020 Rs. 20,000/- dated 26-06-2020 (#1924016) + 30,000/- (#1924026) Form 5D	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.	**Approved with innovator's specification.**

998.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Favirant 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 15046 dated 24/06/2020 Rs. 50,000/- dated 24-06-2020 (#2024222) Form 5D	10's. 30's. 40's 100's As per SRO	Good GMP compliance, inspection date 24/07/2018	**Approved with innovator's specification.**
999.	M/s High noon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Vipra 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 14130 dated 18/06/2020 Rs. 50,000/- dated 18-06-2020 (Form 5D	14's. 28's As per SRO	The firm has been granted GMP certificate based upon evaluation conducted on 06-7-2017	**Approved with innovator's specification.**
1000	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Favigan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 15168 dated 29/06/2020 Rs. 50,000/- dated 29-06-2020 (#2028815) Form 5D	10's. As per SRO	Inspection date 11/02/2019, the panel recommended issuance of GMP certificate	**Approved with innovator's specification.**
1001	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, Kpk, Pakistan	Avigon 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15173 dated 29/06/2020 Rs. 50,000/- dated 29-06-2020 (0719939) Form 5D	10's. 30's 100's As per SRO	Inspection dated 24-01-2019 concludes that the firm is operating at satisfactory level of GMP compliance.	**Approved with innovator's specification.**
1002	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan	Frovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15171 dated 29/06/2020 Rs. 20,000/- dated 29-06-2020 (#2040311) Form 5	As per SRO	The firm is granted GMP certificate based on inspection dated 20-05-2019. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

1003	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 05, M-2 Pharmazone, 26 Km, Main Sharaqpur Road, Shiakhupura, Pakistan	Favirant 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15170 dated 29/06/2020 Rs. 50,000/- dated 29-06-2020 (# 0797740) Form 5D	As per SRO	Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of formulation.	**Approved with innovator's specification.**
1004	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore	Coinzavir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 16422 dated 08/07/2020 Rs. 50,000/- dated 08-07-2020 (#2042503) Form 5D	14's. 28's As per SRO	GMP inspection date d19-10-2017 satisfactory level of compliance.	**Approved with innovator's specification.**
1005	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi	Favipir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16425 dated 08/07/2020 Rs. 50,000/- dated 08-07-2020 (#1929675) Form 5D	As per SRO	GMP certificate issued on the basis of inspection dated 23.05.2018	**Approved with innovator's specification.**
1006	M/s Siam Pharmaceutical 217, Industrial Triangle, Kahuta Road, Islamabad	Fabi Flu 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16551 dated 09/07/2020 Rs. 50,000/- dated 09-07-2020 (#2043375) Form 5D	7's. 10's. 14's. 20's. ,28's, 30's As per SRO	16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section, to M/s Siam Pharmaceuticals Islamabad	**Approved with innovator's specification.**

1007	M/s Maple Pharmaceutical Pvt Ltd. Plot No 147, Sector 23, Korangi Industrial Area, Karachi, 74900, Pakistan	Favirase 200mg Tablet	Each Film coated Tablet Contains: Favipiravir …200mg	Dy.No. 16552 dated 09/07/2020 Rs. 50,000/- dated 09-07-2020 (#2001190) Form 5	100's As per SRO	GMP certificate issued on 22/01/2020 on basis of inspection conducted on 22/12/2020.	**Approved with innovator's specification.**
1008	M/s Ameer Pharma. 23 KM-Sheikhupura Road, Lahore	Am-Vir 200mg tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 15113 dated 29/06/2020 Rs. 20,000/- (#2001315) + 30,000/- (2001321) dated 29-06-2020 Form 5D	10's. 20's, 30's. 40's 50's. 100's As per SRO	9-12-2019 panel recommend renewal of DML	**Approved with innovator's specification.**
1009	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Fav-200 Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15860 dated 03/07/2020 Rs. 20,000/- dated 02-07-2020 (#2029300) Form 5	As per SRO	24-01-2018 Good level of CGMP Compliance. (Differential fee of Rs. 30,000/- is required to be submitted)	**Approved with innovator's specification.**
1010	M/s Fassgen Pharmaceuticals Plot No. 67/1A, Phase-III, Industrial Estate, Hattar	Novel-Vir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 15803 dated 02/07/2020 Rs. 20,000/- dated 02-07-2020 (#2000218) Form 5	As per SRO	Inspection report dated 14/11/2017, 15 recommendations were made regarding QC, production, microbiological lab, cleaning validation, stability chambers etc. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

1011	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Recovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16007 dated 06/07/2020 Rs. 50,000/- dated 06-07-2020 (#0805592) Form 5D	10's. 20's, 30's. 50's As per SRO	The inspection report dated 02.07.2019 concluded satisfactory level of GMP compliance.	**Approved with innovator's specification.**
1012	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	Favigan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15707 dated 02/07/2020 Rs. 20,000/- dated 02-07-2020 (#1956479) 30,000/- (#2036909) Form 5	As per SRO	The firm was inspected on 21-02-2019 GMP compliance level is rated as Good. Form 5D not submitted	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1013	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Favip 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16553 dated 09/07/2020 Rs. 50,000/- dated 09-07-2020 (#2030652) Form 5D	10's. 20's 14's. 28's 30's. 100's As per SRO	Last inspection dated 10-04-2019 concluded acceptable level of GMP compliance	**Approved with innovator's specification.**
1014	M/s ICI Pakistan Limited., 32/2A, Industrial Estate, Hattar	Fluvir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16003 dated 06/07/2020 Rs. 50,000/- dated 29-06-2020 (#2037761) Form 5D	20's, 30's, 40's As per SRO	Last GMP inspection (M/s ICI Pakistan) was conducted on 25-01-2018 and the report concludes the firm to be GMP Compliant.	**Approved with innovator's specification.**
1015	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad	Favix 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 16708 dated 10/07/2020 Rs. 50,000/- dated 10-07-2020 (#2040583) Form 5D	7's. 10's, 14's. 20's, 28's. 30's, 40's. 50's, 100's. As per SRO	Last GMP inspection conducted on 20-11-2017 firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today.	**Approved with innovator's specification.**

1016	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Fabi Flu 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17063 dated 14/07/2020 Rs. 20,000/- dated 14-07-2020 (#2040294) 30,000/- (# 1926152) dated 7-09-2020 Form 5D	As per SRO	Renewal of DML recommended in the inspection dated 13-02-2019	**Approved with innovator's specification.**
1017	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad	Faravir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 17064 dated 14/07/2020 Rs. 20,000/- (#1936990) dated 14-07-2020 + 30,000/- (#2041013) dated 19-08-2020 Form 5D	20's. 30's 100's As per SRO	Crystollite Pharma: Panel Inspection for renewal of DML conducted on 12-11-2018 & 02-01-2019 unanimously recommends the renewal of DML	**Approved with innovator's specification.**
1018	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore	Favira 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 17305 dated 16/07/2020 Rs. 50,000/- dated 16-07-2020 (#2037402) Form 5D	20's. 40's As per SRO	GMP Certificate issued on the basis of GMP inspection conducted on 1-03-2019	**Approved with innovator's specification.**
1019	M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore	Vevir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17572 dated 20/07/2020 Rs. 50,000/- dated 20-07-2020 (# 1956668) Form 5D	As per SRO	Inspection dated 21-03-2019 the firm is considered to be operating at fair level of GMP compliance.	**Approved with innovator's specification.**
1020	M/s Hygeia Pharmaceuticals. Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad	Hypiravir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17711 dated 21/07/2020 Rs. 20,000/- dated 20-07-2020 (#2039204) Form 5	10's. As per SRO	GMP inspection conducted on 21-09-2017, the firm is considered to be operating at satisfactory level of compliance. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

1021	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Favid 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17714 dated 21/07/2020 Rs. 50,000/- dated 21-07-2020 (#1992348) Form 5D	As per SRO	Last GMP inspection conducted on 10-04-18, and the report concludes acceptable level of compliance	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1022	M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan	Fabiflu 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17713 dated 21/07/2020 Rs. 20,000/- dated 21-07-2020 (#2048923) Form 5	As per SRO	Inspection date 08/10/2018, the firm was found working in compliance to GMP. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1023	M/s Amson Vaccines & Pharma Pvt Ltd 110-111. 152-156, Industrial Triangle, Kahuta Road, Islamabad	Ampiravir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 17448 dated 17/07/2020 Rs. 20,000/- dated 17-07-2020 (#2017953) Form 5	As per SRO	Inspection date 04/02/2020, the panel recommended renewal of DML. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1024	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700	Favipir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17447 dated 17/07/2020 Rs. 50,000/- dated 16-07-2020 (#2025382) Form 5D	10's As per SRO	Last inspection report dated 02/05/18 concluding as under: ―The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm	**Approved with innovator's specification.**
1025	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Favisir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 17446 dated 17/07/2020 Rs. 50,000/- dated 14-07-2020 (#1952628) Form 5D	10's. 30's As per SRO	Dated; 08-07-2019 & 25-07-2019 satisfactory level of GMP compliance	**Approved with innovator's specification.**

1026	M/s Paramount Pharmaceutic alPlot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Favi 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17573 dated 20/07/2020 Rs. 20,000/- dated 20-07-2020 (#20381510) Form 5	As per SRO	GMP certificate issued on 28/02/2019. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1027	M/s Medisave Pharmaceutic als. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Covir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 17872 dated 22/07/2020 Rs. 20,000/- dated 22-07-2020 (1995057) Differential fee of Rs. 30,000/- (#1995060) dated 25 Aug 2020 Form 5D	As per SRO	Inspection date 11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1028	M/s Mediceena Pharma. 27 Km, Raiwind Road, Lahore, Pakistan	Medipir a 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 17873 dated 22/07/2020 Rs. 20,000/- dated 21-07-2020 (#2045870) 30,000/- (# 2046905) dated 8-09-2020 Form 5	10's. 20's, 100's, 500's As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 24-9-2019. Need to submit form 5D	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1029	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Frovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18211 dated 24/07/2020 Rs. 50,000/- dated 24-07-2020 (2029927) Form 5D	As per SRO	Last inspection report dated 29-01-2018, GMP are rated as Good.	**Approved with innovator's specification.**
1030	M/s Liven Pharmaceutic als Pvt Ltd. 49 km, Lahore Multan Road.	Favi-Tab 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18213 dated 24/07/2020 Rs. 50,000/- dated 24-07-2020 (#2037403) Form 5D	10's. 30's As per SRO	GMP certificate issued on 31/07/2019 on the basis of inspection conducted on 03/07/2019.	**Approved with innovator's specification.**

1031	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Favir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18069 dated 23/07/2020 Rs. 50,000/- dated 23-07-2020 (#2043886) Form 5D	14's. 28's As per SRO	GMP certificate issued on 27/07/2018 on the basis of inspection conducted on 11/07/2018.	**Approved with innovator's specification.**
1032	M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi	Favip 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18069 dated 23/07/2020 Rs. 50,000/- dated 23-07-2020 (#1997141) Form 5D	As per SRO	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.	**Approved with innovator's specification.**
1033	M/s Rogen Pharmaceuticals. Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad	Favigen 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18378 dated 27/07/2020 Rs. 20,000/- dated 27-07-2020 (2038163) Form 5	10's. 20's, 30's, 50's, 100's As per SRO	Inspection date 25/01/2019, The firm is operating in compliance with GMP. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1034	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan	Favir 200mg Tablet	Each Film coated Tablet Contains: Favipiravir …200mg	Dy.No. 18536 dated 28/07/2020 Rs. 50,000/- dated 28-07-2020 (#1928839) Form 5D	14's. 28's As per SRO	Certificate of GMP Issued on 19-10-2019	**Approved with innovator's specification.**
1035	M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot	Favipin 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18535 dated 28/07/2020 Rs. 20,000/- dated 28-07-2020 (2039205) Form 5	14's. 28's As per SRO	New License (letter issuance date: 29th August 2018) GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

						requisite for manufacturing of pharmaceuticals. (Differential fee of Rs. 30,000/- is required to be submitted)	
1036	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi	Favigan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18537 dated 28/07/2020 Rs. 50,000/- dated 28-07-2020 (#0040535) Form 5D	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.	**Approved with innovator's specification.**
1037	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan	Curavir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18694 dated 29/07/2020 Rs. 50,000/- dated 29-07-2020 (#2036769) Form 5D	As per SRO	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.	**Approved with innovator's specification.**
1038	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700	Favir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18691 dated 29/07/2020 Rs. 50,000/- dated 29-07-2020 (#1909746) Form 5D	7's. 10's. 14's. 20's, 30's. As per SRO	Last inspection report dated 30-04-18 with the remarks level of gmp is rated as good. "GMP Certificate issued on 15-12-2017"	**Approved with innovator's specification.**
1039	M/s Curatech Pharma Pvt Ltd. 35-Km, Multan Road, Lahore	Fluvid 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18689 dated 29/07/2020 Rs. 20,000/- dated 29-07-2020 (#0744236) Form 5D	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

1040	M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi	Infuvir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18692 dated 29/07/2020 Rs. 20,000/- dated 29-07-2020 (#1908234) 30,000/- Dated 28 Aug 2020 (#1908245) Form 5D	10's. 20's, 30's, 40's As per SRO	Last inspection was conducted on 15-07-2019 with the following remarks: Based on the above observations the panel unanimously recommends the firm for the grant of GMP Certificate for export purpose.	**Approved with innovator's specification.**
1041	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi	Favinor 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18761 dated 30/07/2020 Rs. 50,000/- dated 29-07-2020 (#1996267) Form 5D	10's. 20's, 30's, 40's As per SRO	The firm was inspected on 05-07-2018 and conclusion was their current GMP is rated as GOOD.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1042	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore	Avipar 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 18768 dated 30/07/2020 Rs. 20,000/- dated 30-07-2020 (#2016692) Form 5	10's. 20's, 30's, 40's 50's As per SRO	The firm was inspected on 13.09.2019 the following recommendations: The panel of inspector recommends the renewal of DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1043	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	BJ-Gan 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18769 dated 30/07/2020 Rs. 20,000/- dated 30-07-2020 (#1999961) Form 5	As per SRO	Inspection date 15/01/2020. Overall satisfactory at the time of inspection. (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

1044	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi	Ferrari tablet 200mg	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18777 dated 30/07/2020 Rs. 20,000/- dated 30-07-2020 (#1908530) Form 5	As per SRO	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)" (Differential fee of Rs. 30,000/- is required to be submitted)	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1045	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Fav-600 Tablet	Each Film Coated Tablet Contains: Favipiravir …600mg	Dy.No. 15861 dated 03/07/2020 Rs. 50,000/- dated 02-07-2020 (#2029295) Form 5D	As per SRO	Evidence of RRA and Me too	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
1046	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi	Indopavir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir …200mg	Dy.No. 15447 dated 30/06/2020 Rs. 50,000/- (#2026671) dated 30-06-2020 Form 5D	As per SRO	Last inspection report 16-8-2017 firm was considered to be operating at an acceptable level of compliance with GMP.	**Approved with innovator's specification.**
1047	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	Fabiflu 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 15443 dated 30/06/2020 Rs. 20,000/- (#2038125) dated 30-06-2020 Form 5D	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.	**Approved with innovator's specification.**
1048	M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D Block C, Faisal Town, Lahore, Pakistan By	Favipira 200mg Tablet	Each Tablet Contains: Favipiravir … 200mg	Dy.No. 13767 dated 16/06/2020 Rs. 50,000/- dated 16-06-2020 (#2043426) Form 5A	As per SRO	COPP: (Original) embassy attested Issued by: Gov of the "People's Republic of Bangladesh" COPP Certificate #:	**Approved with innovator's specification as per Import Policy for Finished Drugs.**

	M/s Beacon Pharmaceuticals Limited. Kathali, Bhaluka, Mymensingh, Bangladesh					DA/6-110/2016/2802 Dated: 05-05-2020 GMP in COPP: inspected DSL: provided Stability: data of 3 batches on zone 4 A was submitted Sole agency agreement provided	
1049	M/s Pinnacle Biotech Pvt Ltd. FD-49-50-51-54-A8, Korangi Creek Industrial Park, Karachi-75190, Pakistan By M/s Atabay Ilac Fabrikasi A.S. Acibadem Koftuncu Sok.No134718 Kadikoy, Istanbul	Favicovir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir … 200mg	Dy.No. 18538 dated 28/07/2020 Rs. 100,000/- dated 28-07-2020 (#0566476) Form 5A	40's As per SRO	COPP: (Not attached) Issued by: turkey Stability not attached No sole agency agreement	**Decision: Deferred for the following:** • **Submission of stability studies of all the pack sizes applied.** • **Submission of sole agency agreement** • **Submission of original, legalized and valid COPP mentoning the expiry date.** • **And further delibration regarding approval of an imported product.**

Following applications has been received on Form-5/Form 5-D instead of Form 5-F as per details mentioned against each.

S. No.	**Name of applicant**	**Brand Name**	**composition**	**Diary no. Date /Fee & Date/ form**
1050.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore	EAC 1g/327mg/4mg500mg/10mg Tablet	Each Tablet Contains: Calcium Lactate Gluconate…1g Calcium Carbonate…34mg Vitamin D…34mg Vitamin C…500mg Vitamin B6…100mg	Dy.No. 15568 dated 01/07/2020 Rs. 20,000/- dated 04-06-2020 Form 5

1051.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore	ACC Chewable Tablet	Each Tablet Contains: Calcium Lactate Gluconate…1g Calcium Carbonate…34mg Vitamin D3…4mg Vitamin C…50mg Vitamin B6…10mg	Dy.No. 15569 dated 01/07/2020 Rs. 20,000/- dated 04-06-2020 Form 5
1052.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Meprox Plus 250/100 mg Tablet	Each Film Coated Tablet Contains: Atovaquone…250mg Proguanil Hcl…100mg	Dy.No. 15167 dated 29/06/2020 Rs. 20,000/- dated 29-06-2020 Form 5
1053.	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Ivermik 3mg Tablet	Each Uncoated Tablet Contains: Ivermectin…3mg	Dy.No. 14748 dated 24/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1054.	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Ivermik 6mg Tablet	Each Uncoated Tablet Contains: Ivermectin…6mg	Dy.No. 14746 dated 24/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1055.	M/s Radiant Pharma Pvt Ltd.43-E, Sundar Industrial Estate, Lahore	Merotin 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14518 dated 23/06/2020 Rs. 20,000/- dated 23-06-2020 Form 5
1056.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	IverSaf 12mg Tablet	Each Tablet Contains: Ivermectin…12mg	Dy.No. 14359 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1057.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	IverSaf 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 14358 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1058.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	IverSaf 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14357 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1059.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Covectin 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14227 dated 19/06/2020 Rs. 20,000/- dated 17-06-2020 Form 5
1060.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Revexs 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 13773 dated 16/06/2020 Rs. 20,000/- dated 16-06-2020 Form 5
1061.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Revexs 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 13772 dated 16/06/2020 Rs. 20,000/- dated 16-06-2020 Form 5

1062.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Ivermec 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14522 dated 23/06/2020 Rs. 20,000/- dated 23-06-2020 Form 5
1063.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Ivermec 12mg Tablet	Each Tablet Contains: Ivermectin…12mg	Dy.No. 14521 dated 23/06/2020 Rs. 20,000/- dated 23-06-2020 Form 5
1064.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Ivermec 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 14520 dated 23/06/2020 Rs. 20,000/- dated 23-06-2020 Form 5
1065.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Ivertin 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 14524 dated 23/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1066.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Ivertin 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14523 dated 23/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1067.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Covectin 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 14228 dated 17/06/2020 Rs. 20,000/- dated 19-06-2020 Form 5
1068.	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Ectime 6mg Tablet	Each Tablet Contains: Ivermectin…6mg	Dy.No. 14292 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1069.	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Ectime 3mg Tablet	Each Tablet Contains: Ivermectin…3mg	Dy.No. 14291 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1070.	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi	Covimac 6mg Tablet	Each Tablet Contains: Ivernectin…6mg	Dy.No. 17710 dated 21/07/2020 Rs. 20,000/- dated 20-07-2020 Form 5
1071.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Dexasone 2mg Tablet	Each Tablet Contains: Dexamethasone…2mg	Dy.No. 14290 dated 22/06/2020 Rs. 20,000/- dated 22-06-2020 Form 5
1072.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Dexco Injection	Each ml Contains: Dexamethasone Phosphate Eq. to Dexamethasone Sodium Phosphate 4.4mg…4mg	Dy.No. 16002 dated 06/07/2020 Rs. 20,000/- dated 26-06-2020 Form 5

1073.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Dexco 0.5mg Tablet	Each Tablet Contains: Dexamethasone…0.5mg	Dy.No. 16001 dated 06/07/2020 Rs. 20,000/- dated 26-06-2020 Form 5
Decision: Registration Board deferred above cases and directed the firms to apply on Form-5F.				

Item No. 2: Agenda of Evaluator PEC-VII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

1074.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Aultolax 4mg Injection
	Composition	Each 2 ml Injection Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 16521 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900766)
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2 ml glass ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	THIOCOLCHICOSIDE PHARMY II 4 mg/2 ml, solution injectable ampule. ANSM approved
	Me-too status	Myolax Injection. Reg. No. Reg. No. 69277
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1075.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Athancinol Injection
	Composition	Each 4ml Injection Contains: Phloroglucinol Hydrated…40mg Trimethylphloroglucinol….0.04mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14904 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902260)
	Pharmacological Group	Antispasmodic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	The firm revised there form 5 and method of manufacturer from Each 4ml Injection Contains: Phloroglucinol Hydrated…40mg

		Trimethylphloroglucinol….0.04mg To Each 4ml Injection Contains: Phloroglucinol dihydrated…40mg (eq to 31.12 mg anhydrous phloroglucinol) Trimethylphloroglucinol….0.04mg which is according to the reference product with fee of 5000/- (#2038551) dated 03/9/2020
	Decision: Deferred for consideration on its turn.	
1076.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Suxamethonium 50mg Injection
	Composition	Each ml Injection Contains: Suxamethonium chloride …50mg (IV/IM)
	Diary No. Date of R& I & fee	Form-5 Dy. No 16548 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1900797)
	Pharmacological Group	Antispasmodic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	2 ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Suxamethonium chloride 100 mg/2 ml injection 2m1, clear glass ampoules, glass type I (MHRA approved)
	Me-too status	Suxal Injection 100mg/ 2ml of M/s Global Pharma (Reg. # 026629)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1077.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Transalta 250mg/5ml Injection
	Composition	Each 5ml Injection Contains: Tranexamic Acid…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14916 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902375)
	Pharmacological Group	Haemostatic/ Anti-Fibrinolytic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved
	Me-too status	Dravix 250mg/5ml Injection of Getz Pharma Karachi
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1078.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Moxid 400mg Tablets
	Composition	Each Film Coated Tablet Contains:

		Moxifloxacin as Hcl…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14907 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902267)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1x5's As per SRO
	Approval status of product in Reference Regulatory Authorities	AVELOX (moxifloxacin as hydrochloride) 400mg tablets, film-coated. USFDA approved
	Me-too status	G-Mox 400 mg Tablets by M/s Reliance Pharma, Reg. No. 72148
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1079.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Spas 40mg Tablets
	Composition	Each Film Coated Tablet Contains: Otilonium Bromide…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16508 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902374)
	Pharmacological Group	anticholinergic, quaternary ammonium compounds
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasmomen of Italy
	Me-too status	Spasmomen tablet 40mg of Pharmatech.
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1080.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Levo 250mg Tablets
	Composition	Each Film Coated Tablet Contains: Levofloxacin as hemihydrate…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16526 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1900773)
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 250mg By Actavis Group United Kingdom (MHRA)
	Me-too status	Leflox Tablets 250mg By Getz
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	

	Decision: Deferred for consideration on its turn	
1081.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Tazo 2mg Tablets
	Composition	Each Film Coated Tablet Contains: Tizanidine HCL Eq. to…2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16490 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1902355)
	Pharmacological Group	Muscle relaxant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine 2mg Tablets by M/s Actavis UK Ltd (MHRA)
	Me-too status	Musidin 2mg Tablet by M/s Martin Dow (Reg# 027218)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1082.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Tazo 4mg Tablets
	Composition	Each Film Coated Tablet Contains: Tizanidine HCL Eq. to…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16567 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902373)
	Pharmacological Group	Muscle relaxant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine 4mg Tablets by M/s Actavis UK Ltd (MHRA)
	Me-too status	Musidin 4mg Tablet by M/s Martin Dow (Reg#037105)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1083.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Aultaroxit CR 12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Paroxetine Hcl Eq. to Paroxetine…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16491 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1902356)
	Pharmacological Group	SSRI
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet by M/s Apotex Technologies, USA.
	Me-too status	Paroxin CR 12.5mg Tablet by M/s Sharooq Pharmaceuticals
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	The firm revised there form 5 and method of manufacturer from Each Film Coated Tablet Contains: Paroxetine Hcl Eq. to Paroxetine to Each enteric film coated controlled release tablet contains Paroxetine (as hydrochloride) which is according to the reference product with fee of 5000/- (#1926488) dated 17/8/2020
	Decision: Deferred for consideration on its turn	
1084.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Diclo K 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16549 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1900798)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Potassium 50mg Film Coated Tablets by M/s Accord Healthcare Limited, MHRA
	Me-too status	NOREX TABLETS 50mg tablets by M/s Alen Pharmaceuticals (Pvt) Ltd, Reg. No. 3172
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1085.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Letro 2.5mg Tablets
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14896 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902385)
	Pharmacological Group	Non-Steroidal aromatase inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	FEMARA letrozole 2.5mg coated tablet by Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved)
	Me-too status	Femara 2.5mg Tablet by Novartis (Reg. No. 021129)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	

	Decision: Deferred for consideration on its turn	
1086.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Piroxiwen 20mg Tablets
	Composition	Each Tablet Contains: Piroxicam Betacyclodextrin…20mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 16520 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900765)
	Pharmacological Group	Non-Steroidal aromatase inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PIROXICAM G GAM 20 mg, scored table (ANSM approved)
	Me-too status	Piroxibet 20mg Tablets of M/s Lawari International (Reg. # 054939)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1087.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Soda 200mg Tablets
	Composition	Each Film Coated Tablet Contains: Sodium Valproate…200mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 16518 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900763)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Epilim 200 Gastro-resistant tablets (MHRA)
	Me-too status	Epilim E.C 200mg Tablet by Sanofi (#058501)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	The firm revised there form 5 and method of manufacturer from Each Film Coated Tablet Contains: Sodium Valproate to Each gastro resistant coated tablet contains Sodium Valproate which is according to the reference product with fee of 5000/- (#2038553) dated 03/9/2020
	Decision: Deferred for consideration on its turn	
1088.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Quepine 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16515 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900760)

	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SEROQUEL® (quetiapine fumarate). USFDA approved
	Me-too status	Ziapine XR150mg Oral Tablets Reg. No. 78755
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1089.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Pentrex 40mg Tablets
	Composition	Each gastro resistant Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16492 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902357)
	Pharmacological Group	Proton pump inhibitor
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg gastro resistant Tablet (MHRA Approved)
	Me-too status	Pantopraz 40mg Tablet M/s Klifton Pharma,
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	In RRA its gastro resistant not enteric coated so firm revised their formulation from enteric coated to gastro resistant tablet by paying fee of 5000/- (#1926490) dated 20 aug 2020.
	Decision: Deferred for consideration on its turn	
1090.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Leflunomalt 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Leflunomide…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16550 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900799)
	Pharmacological Group	Immunosuppressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ARAVA 20 mg film-coated tablet by Sanofi (ANSM approved)
	Me-too status	Lefluno Tablet of M/s Caraway Pharma 050063
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1091.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan

	Brand Name +Dosage Form + Strength	Cipro 500mg Tablets
	Composition	Each Film coated Tablet Contains: Ciprofloxacin HCL Eq. to Ciprofloxacin…500mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 16538 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1900787)
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin tablets 500mg of M/s Special Concept Development (UK MHRA Approved)
	Me-too status	Axcin Tablets 500mg of M/s Novartis Pharmaceuticals
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1092.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Artho 75/200 mg Tablets
	Composition	Each Film Coated Tablet Contains: Diclofenac Sodium…75mg Misoprostol…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16500 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902366)
	Pharmacological Group	Anti-rheumatic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Arthrotec 75 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too status	Arsofin Tablets by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Reg. no. 48013
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	Firm innitialy apllied as Each Film Coated Tablet Contains Diclofenac sodium…..75mg Misoprostol…….200mcg Moreover, Misoprostol requires special storage Conditions 2-80C. On communication firm submit revised formulation as per the composition of reference product given in the following along with the submission of requisite fee of 5000/- (#1926474) dated 20 aug 2020; Each Film Coated Tablet Contains: Diclofenac Sodium (enteric coated core)…….…75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg In RRA the product is approved as inner enteric coated layer of diclofenac sodium surrounded by misoprostol dispersion coating but the firm applied as film coated tablet.
	Decision: Deferred for consideration on its turn	

1093.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Ceflar 250mg Tablets
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14902 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902266)
	Pharmacological Group	Macrolide
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 250 mg of Sandoz (USFDA Approved)
	Me-too status	Clarmark 250mg tablet Of M/S Wel Mark Pharmaceutical
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1094.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Aultopride 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Itopride HCL…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14903 dated 07-03-2019 Rs.20,000/- Dated 07-03-201 (#1902255)
	Pharmacological Group	Prokinatic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 50mg Tablet by Abbott (PMDA approved)
	Me-too status	Itoguard Tablet of M/s Macter International Karachi (Reg.#055753)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	The firm revised there form 5 and method of manufacturer from Itopride to Itopride HCL which is according to the reference product with fee of 5000/- (#1926489) dated 17/8/2020
	Decision: Deferred for consideration on its turn	
1095.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Cipro 250mg Tablets
	Composition	Each Film coated Tablet Contains: Ciprofloxacin HCL Eq. to Ciprofloxacin…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14925 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902384)
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin tablets 250mg of M/s Special Concept Development (UK MHRA Approved)
	Me-too status	Axcin Tablets 250mg of M/s Novartis Pharmaceuticals
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1096.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Levo 500mg Tablets
	Composition	Each Film Coated Tablet Contains: Levofloxacin as hemihydrate…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14923 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902382)
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 500mg of M/s Actavis Group United Kingdom (MHRA Approved)
	Me-too status	Leflox Tablets 500mg of M/s Getz Pharma
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1097.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Stowel 10mg Tablets
	Composition	Each Film coated Tablet Contains: Escitalopram as Oxalate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14931 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902274)
	Pharmacological Group	Antidepressant (SSRIs)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Escitalopram by cresent pharma Approved by MHRA of UK
	Me-too status	Zavesca tablet 10mg of Getz Pharma. (Reg.#045279)
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1098.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Dimecrotic Acid 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Dimecrotic Acid…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16539 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#1900788)
	Pharmacological Group	Gastrointestinal drugs Cholagogues & hepatic preparations

	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Hepadial 50mg TABLETS (Hilton Pharma), Reg. No. 16850
	GMP status	DML issued on 5th March, 2019.
	Remarks of Evaluator VII	Reference in RRA needed, provided reference of fisiobil spain can't be verified and in ANSM HEPADIAL 50 mg, coated tablet contains magnesium dimecrotate
	Decision: Deferred for consideration on its turn	
1099.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Osicare Plus Tablet
	Composition	Each Tablet Contains: Glucosamine sulphate…500mg Chondrotoin sulphate…400mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13374 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0845203)
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, nonsteroids
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Gevolox Ch Tablets of M/s Hilton Pharma (Reg. # 039688)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	Previously firm applied as each Tablet Contains: Glucosamine sulphate…750mg Chondrotoin sulphate…600mg which is not present in RRA so firm revised its formulation as Each Tablet Contains: Glucosamine sulphate…500mg Chondrotoin sulphate…400mg according to RRA with due fee of 20,000/- (#1983273) dated 26 aug 2020. Firm also requested to change its barand name to "Jovecare tablets"
	Decision: Deferred for consideration on its turn	
1100.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Afexdine 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine Hcl…120mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13364 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900441)
	Pharmacological Group	Antihistamines for systemic use
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Fexotabs 120 mg tablet Approved in TGA
	Me-too status	Epodin 120mg Tablet M/s Epoch Pharma (#52778)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1101.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Andreprol 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol Tartrate…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13378 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0845207)
	Pharmacological Group	Beta blocking agents, selective
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metoprolol Tartrate 100 mg Film-coated Tablets. MHRA approved
	Me-too status	Dronic 100mg Tablets, film coated. Reg. No. 81425
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1102.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Alpharich 0.5mcg Tablet
	Composition	Each Tablet Contains: Alfacalcidol…0.5mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13362 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588348)
	Pharmacological Group	Beta blocking agents, selective
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Alfacalcidol tablet 0.25mcg PMDA Japan approved
	Me-too status	Alfasta Tablet 0.25mcg by M/s Star Labs, Reg. No. 81398
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1103.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arremide 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50 mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 13355 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588341)
	Pharmacological Group	Antiepilaptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 50mg Tablet Atco Lab. Karachi. (Reg. # 075947)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1104.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arremide 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13354 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588340)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of UCB Inc, USFDA Approved.
	Me-too status	Lacolep tablet of Hilton Pharma (Reg. No# 073858).
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1105.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arremide 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…150mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13356 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588342)
	Pharmacological Group	antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 150mg Tablet Atco Lab. Karachi. (Reg.#075949)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.

	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1106.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Thioside 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13346 dated 07-03-2019 Rs.20,000/- Dated 07-03-2 (#0846646)
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYOPLEGE 4 mg hard capsule of M/s GENEVRIER SA Laboratories approved by ANSM of France
	Me-too status	Muscodid 4mg Capsule M/s Regal Pharmaceuticals, Rawat (Reg #081968)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1107.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Afexdine 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine Hcl…60mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13363 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588349)
	Pharmacological Group	Other antihistamines for systemic use
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FEXOTABS fexofenadine hydrochloride 60mg tablet blister pack.TGA approved
	Me-too status	Vigil Tablets by Tabros Pharma. (Reg. No. 39776)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1108.	Duplicate with serial no. 1109.	
1109.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Andreprol 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol Tartrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13377 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902392)
	Pharmacological Group	Beta blocking agents, selective
	Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metoprolol Tartrate 50 mg Film-coated Tablets. MHRA approved
	Me-too status	Mepresor 50mg Tablets, film-coated. Reg. No. 36124
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1110.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Afexdine 180mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine Hcl…180mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13365 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900442)
	Pharmacological Group	H1 receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine hydrochloride film coated tablet 180mg by M/s Cipla (MHRA Approved)
	Me-too status	Epodin 180mg Tablet by M/s Epoch Pharmaceutical, Reg. No. 58058
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1111.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Misonac Tablet
	Composition	Each Tablet Contains: Paracetamol…500mg Caffeine…65mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13349 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0846648)
	Pharmacological Group	Analgesic and CNS Stimulent
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's, 100's, and 200's As per SRO
	Approval status of product in Reference Regulatory Authorities	Panadol Extra Advance 500 mg/65 mg Film Coated Tablets by M/s GSK, MHRA Approved. Paracetamol and caffeine 500mg/65mg soluble tablets (MHRA Approved)
	Me-too status	Cafimol Extra Tablets uncoated. Zinta Pharmaceutical Industry (038898) Me-too Status Paratol Extra tablet by M/s Highnoon (Reg.# 13346)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.

	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1112.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Siliptin-M 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Sitagliptin Phosphate Monohydrate…50mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13365 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0845204)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1113.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Siliptin-M 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Sitagliptin Phosphate Monohydrate…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13375 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0845205)
	Pharmacological Group	Anti diabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too status	Sitaglip-Plus Tablet 50/1000 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53404
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1114.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Utrobin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin as Succinate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13369 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900446)
	Pharmacological Group	Muscarinic antagonist

	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too status	Solifen Tablet 10mg by M/s GetzPharma, Reg. No. 61203
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1115.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Nebilol 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Nebivolol as Hcl…5mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13338 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0846638)
	Pharmacological Group	Beta-1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic 5 mg Tablet (USFDA Approved)
	Me-too status	Nabil Tablets 5mgM/s. Getz Pharma
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1116.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Klomifen 50mg Tablet
	Composition	Each uncoated Tablet Contains: Clomifene Citrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13373 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900450)
	Pharmacological Group	Beta-1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	GENRX CLOMIPHENE clomifene citrate 50mg Uncoated TGA Approved.
	Me-too status	Florid 50mg Tablet M/s Opal Labs, Karachi 075806
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1117.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arecrip 2.5mg Tablet

	Composition	Each Tablet Contains: Bromocriptine as Mesylate…2.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13370 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900447)
	Pharmacological Group	Prolactine inhibitor/ Dopamine Receptor Agonist
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Bromocriptine 2.5mg Tablets by M/s. Meda Pharma, MHRA approved
	Me-too status	Parlodel 2.5 mg tablet by M/s Novartis (Reg#004714)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1118.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arrizin 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine as Hcl…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13336 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0846636)
	Pharmacological Group	Muscle relaxant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's as per SRO
	Approval status of product in Reference Regulatory Authorities	Zanaflex® (tizanidine hydrochloride) uncoated tablets, USFDA Approved
	Me-too status	Tizax 4mg Tablet by Searle (#076022)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	Initialy firm applied as Each Tablet Contains: Tizanidine as Hcl…6mg but this strength is not available in RA so firm revised its formulation and strength as Each Tablet Contains: Tizanidine as Hcl…4mg with fee of 20,000/- (#1983274) dated 26 aug 2020
	Decision: Deferred for consideration on its turn.	
1119.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arractam 250 mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13360 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588343)
	Pharmacological Group	Anti-Epileptic
	Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Levetiracetam zentiva 250 mg of MHRA Approved
	Me-too status	Levep 250mg Tablet by Hilton Pharma (Reg. No. 053348
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1120.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arractam 750mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…750mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13358 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588345)
	Pharmacological Group	Anti-Epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA tablets USFDA Approved
	Me-too status	Lepsira 750mg tablets by Scilife Pharma (Reg. 100439)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	
1121.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arractam 1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13359 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0588346)
	Pharmacological Group	Anti-Epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA (250mg, 500mg, 750mg, 1000mg) film coated tablets USFDA Approved
	Me-too status	Elicia 1000mg Tablet of Martin Dow (Reg.#081157)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn.	

1122.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Utrobin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin as Succinate…5 mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 13368 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1900445)
	Pharmacological Group	Muscarinic antagonist
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vesicare (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too status	Solifen Tablet 5mg by M/s GetzPharma, Reg. No. 61202
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1123.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Misonac plus Tablet
	Composition	Each Tablet Contains: Paracetamol…500mg Caffeine…65mg Chlorpheniramine (Maleate)…….2 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13349 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#1902392)
	Pharmacological Group	Analgesic and CNS Stimulent
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Hesmol Extra tablets of Wisdom Pharmaceuticals
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of Evaluator [VII]	Evidence in RRA
	Decision: Deferred for consideration on its turn.	
1124.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gentasis 80mg/2ml Ampoule
	Composition	Each 2ml Vial Contains: Gentamicin as Gentamicin Sulphate…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10765 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019 (#0703856)
	Pharmacological Group	Aminoglycoside Antibacterial
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	25's As per SRO

	Approval status of product in Reference Regulatory Authorities	Cidomycin 80mg/2ml Solution for Injection (5 x 2ml colourless glass ampoules (Type I) by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too status	Refobacin 80mg/2ml Injection by AD Marker Quetta (Reg. #006473)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1125.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lexus 20 mg
	Composition	Each 2ml Vial Contains: Furosemide…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17387 dated 07-03-2019 Rs.20,000/- Dated 05-03-2019 (#0826527)
	Pharmacological Group	Loop Diuretics
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	2 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Furosemide 20mg /2ml solution for Injection (MHRA approved)
	Me-too status	Lasix Injection of Sanofi Aventis (Reg#000230)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1126.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Metolide 10mg/2ml Ampoule
	Composition	Each 2ml Ampoule Contains: Metoclopramide as Metoclopramide Hcl…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17392 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0761625)
	Pharmacological Group	Antiemetic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Vominor 10mg Injection of Nortech Pharmaceuticals
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1127.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Atropine 1mg/ml Injection
	Composition	Each ml Ampoule Contains: Atropine Sulphate…1mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 17388 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0761616)
	Pharmacological Group	Anti- cholinergic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Atropine Sulfate Injection 1mg in 1 ml (MHRA)
	Me-too status	Atropine Injection By M/s. Alina: 049677
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1128.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	D-Spa 40mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Drotaverine Hcl…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17396 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0839015)
	Pharmacological Group	Antispasmodic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in 3 European countries
	Me-too status	NO-SPA INJECTION. Reg No. 08296
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn.	
1129.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ketamile 500mg/10ml Ampoule
	Composition	Each 10ml Vial Contains: Ketamine as Ketamine Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17395 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826521)
	Pharmacological Group	General anesthetics (N01AX03)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10ml glass ampoule, As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketalar USFDA Approved 10-mL multi-dose vial
	Me-too status	Ketarol Injection 50mg/ml M/s Global Pharmaceuticals, Islamabad; 026630
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	In RRA its in Vile

	Decision: Deferred for consideration on its turn.	
1130.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Avebion Ampoule
	Composition	Each 3ml Ampoule Contains: Thiamine Hcl…100mg Pyridoxine Hcl…100mg Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17379 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826520)
	Pharmacological Group	B-complex vitamin
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurobion Injection by M/s Merck (Germany) Merck
	Me-too status	Neurobion Injection by Merck (Reg. No. 001485)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn .	
1131.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gravisis 50mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Dimenhydrinate …50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17383 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826524)
	Pharmacological Group	Antiemetic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dimenhydrinate Injection of Fresenius Kabi, USFDA Approved.
	Me-too status	Corinate 50mg/ml Inj. of Asian continental (Reg#057863).
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1132.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Piromax 20mg/ml Injection
	Composition	Each ml Ampoule Contains: Piroxicam…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17389 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0761613)
	Pharmacological Group	Anti-rheumatic
	Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	5's As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status	Salden 20mg Injection of M/s Danas Pharma (Reg.#080373)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1133.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Transit 500mg/5ml Injection
	Composition	Each 5ml Ampoule Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17373 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826522)
	Pharmacological Group	Antifibrinolytic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5's, 10's, 20's as per SRO
	Approval status of product in Reference Regulatory Authorities	CYKLOKAPRON 500mg Solution for Injection by M/s Pfizer Limited, MHRA
	Me-too status	Tremic -500 Injection of M/s M/s Fynk Pharmaceuticals,
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1134.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Transit 250 mg/5ml Injection
	Composition	Each 5ml Ampoule Contains: Tranexamic Acid…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17374 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826523)
	Pharmacological Group	Antifibrinolytic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5's, 10's, 20's As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved
	Me-too status	Dravix 250mg/5ml Injection of Getz Pharma Karachi
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1135.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ketrolav 30mg/ml Ampoule
	Composition	Each ml Ampoule Contains: Ketrolac Trometamol…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17382 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826526)

	Pharmacological Group	Anti-inflammatory and Anti-rheumatic Products, Non-Steroids
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5's, 25's As per SRO
	Approval status of product in Reference Regulatory Authorities	Tora-Dol 30 mg/ml AIFA Approved
	Me-too status	Orkit Injection IV Aulton Pharmaceuticals (080560)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1136.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Kinza 20mg/ml Ampoule
	Composition	Each 1ml Ampoule Contains: Nalbuphine Hcl…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17390 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0841037)
	Pharmacological Group	Potent analgesic.
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5's, 25's As per SRO
	Approval status of product in Reference Regulatory Authorities	NUBAIN – (nalbuphine hydrochloride) injection (1ml ampule), for intramuscular, subcutaneous, or intravenous (USFDA).
	Me-too status	Nalfy Injection 20mg. Reg. No. 81911
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1137.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	D-Fenac 75mg/3ml Injection
	Composition	Each 3ml Ampoule Contains: Diclofenac Sodium…75mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17380 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0826525)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5's, 25's As per SRO
	Approval status of product in Reference Regulatory Authorities	NUBAIN – (nalbuphine hydrochloride) injection for intramuscular, subcutaneous, or intravenous (USFDA).
	Me-too status	Nalfy Injection 20mg. Reg. No. 81911
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1138.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan

	Brand Name +Dosage Form + Strength	Adrenaline 0.1% Injection
	Composition	Each Ampoule Contains: Adrenaline…1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17378 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0761617)
	Pharmacological Group	adrenergic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	100's As per SRO
	Approval status of product in Reference Regulatory Authorities	Adrenaline solution for ijection (MHRA)
	Me-too status	Adrenaline injection by Elite (#026237)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1139.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Codomax 500/15 mg Tablet
	Composition	Each Tablet Contains: Paracetamol…500mg Codeine phosphate hemihydrate…15mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17385 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0841047)
	Pharmacological Group	Opioid analgesic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-codamol 15/500 Tablets of Zentiva Pharma UK Limited
	Me-too status	Lowmol Tablets (Reg. 040426) of Lowit Pharma (Pvt) Ltd
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	In RRA Codeine phosphate hemihydrate not just codien No master formulation and method of manufacturer
	Decision: Deferred for consideration on its turn	
1140.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Montysis 4mg Sachet
	Composition	Each Sachet Contains: Montelukast as Montelukast Sodium oral granules …4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17385 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0841018)
	Pharmacological Group	Leukotriene antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's As per SRO

	Approval status of product in Reference Regulatory Authorities	Singulair Sachet 4mg Granules of Merck, USFDA
	Me-too status	Montiget Sachet of M/s Getz Pharma (Reg.# 044046
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1141.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Stilmix 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zolpidem Tartrate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17385 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0813648)
	Pharmacological Group	Sedative
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Stilnoct (5mg, 10mg) film-coated Tablets by M/s Sanofi, MHRA Approved.
	Me-too status	Olida 10mg Tablets of M/s Glitz Pharmaceuticals, Islamabad (Reg.# 081418)
	GMP status	Inspection dated 28-11-2018 for DML, CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1142.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Eastern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Kinza 10mg/ml Ampoule
	Composition	Each 1ml Ampoule Contains: Nalbuphine Hcl…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 17391 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (#0841036)
	Pharmacological Group	Potent analgesic.
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5's, 25's As per SRO
	Approval status of product in Reference Regulatory Authorities	NUBAIN – (nalbuphine hydrochloride) injection for intramuscular, subcutaneous, or intravenous (USFDA).
	Me-too status	Sonotic injection of M/s Brookes Pharma (Reg. # 057729)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of formulation for nine sections
	Remarks of Evaluator [VII]	
	Decision: Deferred for consideration on its turn	
1143.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals. F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gentasis 80mg/2ml vial

	Composition	Each 2ml Vial Contains: Gentamicin as Gentamicin Sulphate…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10765 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019 (#0842238)
	Pharmacological Group	Aminoglycoside Antibacterial
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	25's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gentamicin 40mg/ml Injection 80 mg/ 2 ml – Clear, Type I glass vials (MHRA Approved)
	Me-too status	Refobacin 80mg/2ml Injection by AD Marker Quetta (Reg. #006473)
	GMP status	CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation for nine sections:
	Remarks of Evaluator [VII]	
	Decision: Approved	
1144.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Alevic Tablet 70mg
	Composition	Each Film Coated Tablet Contains: Alendronate (As Sodium) Trihydrate …70mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9325 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825835)
	Pharmacological Group	Bisphosphonate, for the treatment of bone diseases
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Alendronate sodium 70 mg USFDA Approved
	Me-too status	Bonfit 70mg tablets of M/s Searle Pak (Reg. # 045429)
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	In RRA Alendronate (As Sodium) Trihydrate". On communication the firm change its form 5 and master formulation without fee.
	Decision: Approved	
1145.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Diclo-In 50mg Tablet
	Composition	Each enteric coated tablet contains: Diclofenac Sodium…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9312 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825822)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Voltaren Tablets (25mg & 50mg) enteric coated by M/s NOVARTIS Pharma, TGA Austrailia Approved.
	Me-too status	Diclopal Tablet (delayed released) 50mg by M/s Palpex Pharmaceuticals, Reg. No. 82298
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1146.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Invoflox 500mg Tablet
	Composition	Each Tablet Contains: Levofloxacin as hemihydrate …500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9306 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825812)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levofloxacin (250mg & 500mg) Film-coated Tablets by M/s Accord Healthcare Limited, MHRA Approved
	Me-too status	Cubac Tablets 250mg by M/s Schazoo Labs, Reg. No. 47943
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	In RRA it is approved as film coated tablet
	Decision: Deferred for clarification of applied formulation since reference product is film coated whereas firm has applied for tablet.	
1147.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cyclopin SR 30mg Capsule
	Composition	Each hard gelatin capsule contains: Extended release Cyclo benzaprine HCL…15mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9470 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825815)
	Pharmacological Group	Skeletal Muscle Relaxant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Amrix extended release capsule (15mg, 30mg) by M/s Teva Pharms intl, (USFDA Approved).
	Me-too status	Flexagil XR Capsule 30mg by M/s CCL Pharma (Reg#78920)
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	Source of pellets is vision pharma
	Decision: Approved	
1148.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Repra 20mg Capsule

	Composition	Each Capsule Contains: Rabiprazole sodium as enteric coated pellets …20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9468 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825813)
	Pharmacological Group	Proton pump inhibitors
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Repit by Rabeptaole 20 mg by Sharooq065994
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	Evidence in RRA and Me too needed. (provided reference of Aciphex sprinkle capsule is in 5 and 10 mg)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1149.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Relax Tablet 5/160mg Tablet
	Composition	Each Film coated Tablet Contains: Amlodipine besylate eq to Amlodipine…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 9308 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825818)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge 5/160mg film-coated tablets by M/s Novartis Pharma, USFDA Approved.
	Me-too status	Amsart 5/160mg Tablet by M/s Genetics Pharmaceutical (Pvt) Ltd, Reg. No. 84098
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1150.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Quietus 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…25mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 9322 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825832)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, 200mg) by M/s Aurobindo pharma, MHRA Approved

	Me-too status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hiltonpharma, Reg No. 37684 37685 37690
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1151.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Articam 7.5mg Tablet
	Composition	Each uncoated Tablet Contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9322 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825824)
	Pharmacological Group	Non-steroidal anti-inflammatory drugs (NSAIDs)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MOBIC® (meloxicam) uncoated Tablets 7.5 mg by M/s Boehringer Ingelheim Pharmaceuticals, Inc. USFDA Approved.
	Me-too status	Orthicam Tablet 7.5mg by M/s Linear Parma,, (Reg No. 81878)
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1152.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Invefine 250mg Tablets
	Composition	Each Tablet Contains: Terbinafine as HCL…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9316 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825826)
	Pharmacological Group	Antifungal
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s NOVARTIS PHARMACEUTICALS UK LIMITED, MHRA Approved.
	Me-too status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Reg No. 80847)
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1153.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Articam 15mg Tablet
	Composition	Each Tablet Contains: Meloxicam…15mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9315 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825825)

	Pharmacological Group	Non-steroidal anti-inflammatory drugs (NSAIDs)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MOBIC® (meloxicam) uncoated Tablets 15 mg by M/s Boehringer Ingelheim Pharmaceuticals, Inc.USFDA Approved.
	Me-too status	Mexiran Tablets 15mg by M/s Akson Pharmaceutical (Pvt) Ltd, Reg. No. 29846
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1154.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Urosol 10mg Tablets
	Composition	Each Tablet Contains: Solifenacin as Succinate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9315 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825828)
	Pharmacological Group	Muscarinic antagonist
	Form	Form-5
	Finished product Specifications	Manufacturing specification
	Pack size & Demanded Price	1x10's 2x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too status	Solifen Tablet 10mg by M/s Getz Pharma, Reg. No. 61203
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	In RRA Film coated tablet on communication the firm change its form 5 and master formulation without fee.
	Decision: Deferred for evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1155.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Vital 500mcg Tablet
	Composition	Each sugar-coated tablet contains: Mecobalamine …500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9309 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825819)
	Pharmacological Group	Coenzyme type/Vitamin B12
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan
	Me-too status	Mecomed 500mcg by Global Pharma (Reg. No. 041670)

	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1156.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Invefine 125mg Tablets
	Composition	Each Tablet Contains: Terbinafine as HCL…125mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9309 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0825827)
	Pharmacological Group	Antifungal
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamisil® Tablets 125mg by M/s Novartis Pharmaceuticals Australia Pty Limited, TGA Australia approved.
	Me-too status	Logirid Tablet 125mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80846
	GMP status	13-11-2018, The panel recommended the grant DML.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1157.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	D-Pain Injection
	Composition	Each 2ml contains: Diclofenac Sodium…75mg Lignocaine …20mg (Water for Injection…2ml)
	Diary No. Date of R& I & fee	Form-5 Dy.No 9309 dated 01-03-2019 Rs.50,000/- Dated 5-03-2019 (#0849770)
	Pharmacological Group	NSAID/Local anesthic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5x2 ml 10x2 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac-Mepha 75 ampoules for IM injection (SwissMedics approved)
	Me-too status	Dyclo Plus 2ml Injection by Indus Pharma (#076107)
	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant of DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator [VII]	Total sections: 5 Products on contract: Nil
	Decision: Deferred for capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore	

1158.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Inlife-D Injection 5mg
	Composition	Each ml contains: Cholecalciferol Vit d3…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10366 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019 (#0849768)
	Pharmacological Group	Vitamin D3 analogue
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x1 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator [VII]	Total sections: 5 Products on contract: Nil
	Decision: Deferred for capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore	
1159.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	I-Fort Injection
	Composition	Each 5ml contains: Iron sucrose complex eq to elemental iron…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10367 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019 (#0849769)
	Pharmacological Group	Iron supplement
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer Injection by Vifor (MHRA Approved)
	Me-too status	Vortex 100mg/ 5ml injection of Saturn Pharma
	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator [VII]	Total sections: 5

		Products on contract: Nil
	Decision: Deferred for capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore	
1160.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Bitwel M 500mcg Injection
	Composition	Each ml contains: Mecobalamine.500mcg Water for Injection…1ml
	Diary No. Date of R& I & fee	Form-5 Dy.No 10362 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019 (#0837030)
	Pharmacological Group	Coenzyme Type Vitamin B12
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA Approved
	Me-too status	Mexamine 500mcg/ml Injection of M/s Asian Continental (Pvt.) Ltd, Karachi(Reg. # 057864)
	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator [VII]	Total sections: 5 Products on contract: Nil
	Decision: Deferred for capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore	
1161.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	X-Pain Injection 10mg
	Composition	Each ml contains: Nalbuphine Hcl …10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10361 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019 (#0837029)
	Pharmacological Group	Opioid analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	5x10 ml 10x1 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Nubain Injection Par Pharm Inc USA
	Me-too status	Nalfy Injection of M/s Vision Pharma (Reg. 081912)

	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator VII	No. of drugs on contract basis are Nil and 5 sections are available in the applicant 's firm.
	Decision: Deferred for capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore	
1162.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi By M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Molig Injection
	Composition	Each ml contains: Paracetamol…150mg Water for Injection…1ml
	Diary No. Date of R& I & fee	Form-5 Dy.No 10365 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019 (#0849767)
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	5x 2ml 10x2 ml 50x2 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Pravos 150mg injection by M/s Sami Pharmaceuticals (Pvt) Limited.
	GMP status	M/S s Invictus 13-11-2018, The panel recommended the grant DML. M/S News Pharma GMP Inspection of News Pharma Conducted on 26-4-2018. GMP Certificate is provided.
	Remarks of Evaluator VII	No. of drugs on contract basis are Nil and 5 sections are available in the applicant's firm. The firm change its formulation from Each ml contains: Paracetamol…150mg Lignocaine …20mg Water for Injection…1ml to Each ml contains: Paracetamol…150mg Water for Injection…1ml With revised master formulation and form 5 provided, fee just mentioned but draft not provided, In RRA that revised forumalation could not be confirmed.
	Decision: **Deferred for following reasons:** • **capacity assessment of M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore**	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1163.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Brymol Eye Drops 2/5mg
	Composition	Each ml contains: Brimonidine Tartrate…2mg Timolol as Maleate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 10367 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019 (#0807636)
	Pharmacological Group	Alpha- adrenergic receptor agonist and beta-adrenergic receptor inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Combigan of USFDA approved
	Me-too status	Combigan of M/s Barrett hodgson
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1164.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Nazoline EyeDrops 0.012%
	Composition	Each ml contains: Naphazoline HCL…0.012%
	Diary No. Date of R& I & fee	Form-5 Dy.No 9433 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807632)
	Pharmacological Group	Decongestant
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	15,10, 5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Murine Irritation & Redness Relief (MHRA)
	Me-too status	Naphtears by Novartis pharma (pak) ltd
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1165.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sorsis Cream 50mg
	Composition	Each gram contains: Calcipotriol …50 mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9433 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807639)
	Pharmacological Group	Other antipsoriatics for topical use
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Calcipotriol Cream 50 micrograms/g. MHRA approved
	Me-too status	Calcipot Cream Reg. No. 69823
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1166.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Methlone Cream
	Composition	Each gram contains: Methylprednisolone Acetone…0.1%
	Diary No. Date of R& I & fee	Form-5 Dy.No 9441 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807640)
	Pharmacological Group	Corticosteroids, potent (group III)
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5,10, 15, 20, 25, 30 gm As per SRO
	Approval status of product in Reference Regulatory Authorities	ADVANTAN methylprednisolone aceponate 1mg/g cream by M/s Bayer Australia Ltd (TGA Approved)
	Me-too status	Advantan 0.1% w/w cream by M/s Bayer Health Care (Reg#018644)
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Deferred from confirmation of segregated dispensing booth for steroidal cream as per decision of Licensing Board.	
1167.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Nazoline-P EyeDrops
	Composition	Each ml contains: Naphazoline HCL…0.025% Pheniramine Maleate…0.3%
	Diary No. Date of R& I & fee	Form-5 Dy.No 9434 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807633)
	Pharmacological Group	Corticosteroids, potent (group III)
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	15,10, 5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Naphcon-A by Alkon (USFDA)
	Me-too status	Ocucon-A Eye Drops Farmigea (Reg # 026351)
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1168.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Aclovir Cream 5%
	Composition	Each gram contains: Acyclovir…5%
	Diary No. Date of R& I & fee	Form-5 Dy.No 9442 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807641)

	Pharmacological Group	Antivirals
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2,3,5,10 15 g As per SRO
	Approval status of product in Reference Regulatory Authorities	Zovirax Cream by M/s GlaxoSmithKline MHRA
	Me-too status	Cycloz topical cream by M/s Ferozsons
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1169.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Etrolic Eye Drops
	Composition	Each ml contains: Ketorolac Tromethamine…0.5% (5 mg)
	Diary No. Date of R& I & fee	Form-5 Dy.No 9435 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807634)
	Pharmacological Group	Anti- inflammatory
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketorolac tromethamine 0.5% eye drops by Apotex (MHRA Approved)
	Me-too status	Ketrosan 0.5% Sterile Ophthalmic Solution of M/s Elko Organisation (Reg. # 026391)
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1170.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sorsis B Ointment
	Composition	Each gram contains: Calcipotriol …50 microgram Betamethasone as Dipropionate…0.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9439 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807638)
	Pharmacological Group	Anti- psoriasis
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10, 15,20, 25, 30, 50 gm As per SRO
	Approval status of product in Reference Regulatory Authorities	Dalbecal 50 microgram/ g + 0.5 mg/ g Ointment by M/s Teva UK Limited (MHRA Approved)
	Me-too status	Daivobet Ointment by M/s Zam Zam corporation (Reg #031379)
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1171.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Tevost Eye Drops 40microgram

	Composition	Each ml contains: Travoprost…40microgram
	Diary No. Date of R& I & fee	Form-5 Dy.No 9438 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807637)
	Pharmacological Group	Prostaglandin
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2.5ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Travoprost 40 micrograms/ml eye drops, solution by TevabUK Limited, (MHRA Approved)
	Me-too status	Travop ophthalmic solution 0.004% by Alza Reg. # 081621
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator VII	
	Decision: Approved with innovator's specification.	
1172.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Bexo Eye Drops 0.5%
	Composition	Each ml solution contains: Betaxolol as HCL…0.5%
	Diary No. Date of R& I & fee	Form-5 Dy.No 9436 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019 (#0807635)
	Pharmacological Group	selective beta1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Betaxolol 0.5% Eye Drops MHRA approved
	Me-too status	Betaxolol, 0.5% by Invotek Reg. # 026956
	GMP status	GMP certificate to M/s Jaens Pharmaceuticals was issued on 03/04/2019 issued on the basis of inspection dated 14/01/2019
	Remarks of Evaluator VII	
	Decision: Approved with innovator's specification.	
1173.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Velzim 0.5mg Tablet
	Composition	Each Tablet Contains: Alprazolam…0.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10135 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604889)
	Pharmacological Group	Antidepressant
	Form	Form-5
	Finished product Specifications	USP Specs
	Pack size & Demanded Price	3×10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xanax 0.50mg by M/s Pfizer, MHRA Approved
	Me-too status	Lydia 0.50mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65705
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML Tablet section (Psychotropic) present
	Remarks of Evaluator VII	
	Decision: Approved.	
1174.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK

	Brand Name +Dosage Form + Strength	Condip-D Tablet
	Composition	Each Tablet Contains: Amlodipine besylate…5mg hydrochlorothizaid…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11452 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604875)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Zamlo-H by Zafa Pharma.
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	RRA not found
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1175.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Bromavel 3mg Tablet
	Composition	Each Tablet Contains: Bromazepam…3mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10134 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604884)
	Pharmacological Group	Benzodiazepines
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lexotan (3mg, 6mg) tablets by M/s Roche TGA Australia Approved.
	Me-too status	Lexgit 3mg Tablets by M/s Glitz Pharmaceuticals, Reg. No. 81422
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1176.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Citamode Tablets 10mg
	Composition	Each Tablet Contains: Escitalopram…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11451 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0807635)
	Pharmacological Group	Antidepressants
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cipralex 10 mg film-coated tablets (MHRA Approved)
	Me-too status	Lexopram Tablets 10 mg by Evolution pharma
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Each film coated Tablet Contains:

		Escitalopram (as oxalate)…10mg. Firm has initially applied for uncoated tablet containing escitalopram without oxalate salt. Later the firm revised its formulation as per reference product submitting PKR 20,000/- fee (#2015173) dated 18-08-2020.
	Decision: Approved as each film coated Tablet Contains: Escitalopram (as oxalate)…10mg.	
1177.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPKM/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Esvell 40mg IV Injection
	Composition	Each vial contains Esomeprazole (as sodium)…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10123 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0807635)
	Pharmacological Group	PPI
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s Astrazeneca Pharms (USFDA approved)
	Me-too status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824Lexopram Tablets 10 mg by Evolution pharma
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of Evaluator [VII]	Total sections of convell: 7 sections Total products on toll: Nil
	Decision: Approved with innovator's specification	
1178.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Glimet 1 Tablets 1/500mg
	Composition	Each film coated Tablet Contains: Glimepiride…1mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10123 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0604876)
	Pharmacological Group	Sulfonylureas + Biguanides
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76011 GPRIDE-M SR 1/500mg tablet (bilayer). Reg. No. 76306
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which

		were adopted by the Registration Board in its 275thmeeting
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1179.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Glimet 2 Tablets 1/500mg
	Composition	Each Tablet Contains: Glimepiride…2mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11454 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604877)
	Pharmacological Group	Sulfonylureas + Biguanides
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76012 GPRIDE-M SR 2/500mg tablet (bilayer). Reg. No. 76307
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1180.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Saidu Sharif Swat, KPK
	Brand Name +Dosage Form + Strength	Broven Suspension 100mg/5ml
	Composition	Each 5ml contains: Ibuprofen…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11450 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604873)
	Pharmacological Group	NSAIDs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	IBuprofen 100mg/5ml Oral Suspension of (MHRA Approved)
	Me-too status	Nuprin 100mg Suspension M/s Reign Pharma
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	
	Decision: Approved	
1181.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPKM/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ketvell 30mg Injection
	Composition	Each ampoule contains: Ketorolac Tromethamine…30mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 10120 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0807635)
	Pharmacological Group	NSAIDs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as (I/M)
	Me-too status	Ketomal Injection of M/s Trigon Pharma (Reg. # 074193)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of Evaluator [VII]	Total sections of convell: 7 sections Products: Nil
	Decision: Approved	
1182.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPKM/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mec 500mcg Injection
	Composition	Each 1 ml ampoule contains: Mecobalamine…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10121 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0807635)
	Pharmacological Group	NSAIDs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as (I/M)
	Me-too status	Ketomal Injection of M/s Trigon Pharma (Reg. # 074193)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of Evaluator [VII]	Total sections of convell: 7 sections Product: Nil
	Decision: Approved.	
1183.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Mosif 400mg Tablet
	Composition	Each Film coated Tablet Contains: Moxifloxacin Hcl…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11455 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604878)
	Pharmacological Group	Fluoroquinolones
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	AVELOX (moxifloxacin as hydrochloride) 400mg tablets, film-coated. USFDA approved
	Me-too status	Moxizyan 400mg Tablets, film-coated. Reg. No. 77252
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015174) dated 18-08-2020.
	Decision: Approved	
1184.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velzipine 5mg Tablet
	Composition	Each Tablet Contains: Olanzapine...5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11455 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604885)
	Pharmacological Group	Neuroleptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Olanzapine Actavis 5 mg Film-coated Tablets, from Actavis Group Iceland. PL 30306/0164, MHRA Approved.
	Me-too status	Olanzapine-Sandoz 5mg Tablets. By Novartis Pharma, Karachi. (Reg#064040)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015175) dated 18-08-2020.
	Decision: Approved.	
1185.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velzipine 10mg Tablet
	Composition	Each Tablet Contains: Olanzapine...10 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10138 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604886)
	Pharmacological Group	Neuroleptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Olanzapine Actavis 10 mg Film-coated Tablets MHRA Approved.
	Me-too status	Olanzpine 10 mg Tablets. By: Akson Pharmaceuticals Pvt Ltd. Mirpur. (Reg.#081661)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015176) dated 18-08-2020.
	Decision: Approved	

1186.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPKM/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Swazole 40mg IV Injection
	Composition	Each vial contains Omeprazole as sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10138 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019 (#0807635)
	Pharmacological Group	Proton pump inhibitors
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of applicant (Convell or Goodman) and deposited fee for contract manufacturing.	
1187.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Rel-X Forte Tablet 650mg
	Composition	Each Tablet Contains: Paracetamol…650mg Orphenadrine citrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11456 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604879)
	Pharmacological Group	Skeletal muscle relaxant/Antipyretic Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Nuberol Forte Tablet by M/s Searle Pakistan Ltd,, Reg.#027196
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Evidence in RRA
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1188.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Nac Tablets 100mg
	Composition	Each film coated Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11459 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0807635)
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg film-coated Tablets by M/s Accord Healthcare, MHRA Approved.
	Me-too status	Gratis Tablets 100mg BP by M/s Navegal, Reg. No. 43900
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Firm revised its formulation from uncoated to film coated without providing fee
	Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product.	
1189.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Prelin Plus Capsule 150mg
	Composition	Each Capsule Contains: Pregabalin…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11459 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604887)
	Pharmacological Group	Anti epileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma (#048724)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1190.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Prelin Plus Capsule 75 mg
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11457 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0604880)
	Pharmacological Group	Anti epileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma (#047365)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1191.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Quetil 100mg Tablet
	Composition	Each Tablet Contains: Quetiapine as fumarate…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11446 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0508175)
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, and 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. (37684, 37685, 37690)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	The firm revised their formulation from Quetiapine fumarate uncoated tablet to Quetiapine as fumarate film coated tablet. Without the provision of fee.
	Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product	
1192.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Quetil 25mg Tablet
	Composition	Each Tablet Contains: Quetiapine fumarate…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11445 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0508174)
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, and 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. (37684, 37685, 37690)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	The firm revised their formulation from Quetiapine fumarate uncoated tablet to Quetiapine as fumarate film coated tablet. Without the provision of fee.
	Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product.	
1193.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velresp 2mg Tablet
	Composition	Each Film coated Tablet Contains: Risperidone …2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11447 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0508176)
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's 120/10 tablet
	Approval status of product in Reference Regulatory Authorities	Risperdal 2mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4m g) by M/s Novartis, Reg No. 48832
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML

	Remarks of Evaluator [VII]	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015177) dated 18-08-2020.
	Decision: Approved.	
1194.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velresp 1mg Tablet
	Composition	Each Film coated Tablet Contains: Risperidone …1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11448 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0508177)
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 1mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, Reg No. 48831
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015178) dated 18-08-2020.
	Decision: Approved.	
1195.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velresp 3mg Tablet
	Composition	Each Film coated tablet Contains: Risperidone …3mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11449 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019 (#0508178)
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 3mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, Reg No. 48831
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator [VII]	Firm has initially applied for uncoated tablet. Later the firm revised its formulation as per reference product i.e. film coated tablet submitting PKR 5,000/- fee (#2015179) dated 18-08-2020.
	Decision: Approved.	
1196.	Name and address of manufacturer / Applicant	M/s Convell Laboratories. Swat, KPK
	Brand Name +Dosage Form + Strength	Velzo 10mg Tablet
	Composition	Each film coated tablet Contains: Zolpidem as tartrate…10 mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 10136 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019 (#0807635)
	Pharmacological Group	Antidepressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Stilnoct (5mg, 10mg) film-coated Tablets by M/s Sanofi, MHRA Approved.
	Me-too status	Olida 10mg Tablets of M/s Glitz Pharmaceuticals, Islamabad (Reg.# 081418)
	GMP status	M/S Convell: Panel inspection dated 02-3-2019 for renewal of DML
	Remarks of Evaluator VII	
	Decision: Approved.	
1197.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Renom 1g Injection
	Composition	Each vial contains: Meropenem as trihydrate blended with anhydrous sodium carbonate…1g
	Diary No. Date of R& I & fee	Form-5 Dy.No 13079 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0849676)
	Pharmacological Group	Carbapenem
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM IV (as the trihydrate blended with anhydrous sodium carbonate for re-constitution) of sterile meropenem powder. (USFDA)
	Me-too status	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	M/S Necholas: Last GMP inspection was conducted on 03/08/18 Conclusion: "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule(Cephalosporin) 2- Dry suspension section(Cephalosporin) 3- Dry powder Injectable section(Cephalosporin) 4- Dry powder Injectable section(Carbapenems)" M/S Cure Labortries: Dated 05-03-2019, Issuance of DML in 269th Meeting of CLB.
	Remarks of Evaluator VII	Total sections: 3 Total products on toll: No
	Decision: Deferred for consideration on its turn	
1198.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Renom 500mg Injection
	Composition	Each vial contains: Meropenem as trihydrate…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13078 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0807635)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM IV (as the trihydrate blended with anhydrous sodium carbonate for re-constitution) of sterile meropenem powder. (USFDA)
	Me-too status	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Same As Above
	Remarks of Evaluator [VII]	Total sections: 3 Total products on toll: No
	Decision: Deferred for consideration on its turn	
1199.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Esocure 40mg Injection
	Composition	Each vial contains: Esomeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13942 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0807480)
	Pharmacological Group	Proton pump inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturing specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP status	M/S Vision: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator [VII]	Total sections: 3 Total products on toll: No
	Decision: Deferred for consideration on its turn	
1200.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	P-Role 40mg Injection
	Composition	Each vial contains: Omeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13942 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0807479)
	Pharmacological Group	Proton pump inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturing specicifcations
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP status	M/S Vision: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator [VII]	Total sections: 3 Total products on toll: No
	Decision: Deferred for consideration on its turn	
1201.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Quantum 5mg Injection
	Composition	Each ampoule contains: Cholecalciferol …5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13942 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0807483)
	Pharmacological Group	Vitamin D3 analogue
	Form	Form-5
	Finished product Specifications	Manufacturing specicifcations
	Pack size & Demanded Price	1 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	M/S Vision: GMP inspection dated 11-2-2019 concluding good GMP complaience
	Remarks of Evaluator [VII]	Each Ampoule (1ml) Contains: Cholecalciferol (Vitamin D3)…200,000 IU Eq. to 5mg/ml Total sections: 3 Total products on toll: No
	Decision: Deferred for consideration on its turn	
1202.	Name and address of manufacturer / Applicant	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mecomet 500mcg Injection
	Composition	Each 1ml ampoule contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13942 dated 06-03-2019 Rs.50,000/- Dated 06-03-2019 (#0807481)
	Pharmacological Group	Vitamin D3 analogue
	Form	Form-5
	Finished product Specifications	Manufacturing specifications
	Pack size & Demanded Price	1 ml ampoule type 1 As per SRO
	Approval status of product in Reference Regulatory Authorities	Comezengen injection 500 µg of M/s Tatsumi Chemical (PMDA Japan Approved)
	Me-too status	Flench injection of M/s Tabros Pharma (Reg. # 029050)
	GMP status	M/S Vision: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator [VII]	Total sections: 3 Total products on toll: No

	Decision: Deferred for consideration on its turn	
1203.	Name and address of manufacturer / Applicant	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Spasmed 40mg Injection
	Composition	Each ampoule contains: Pholoroglucinol dihydrate…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10116 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0807635)
	Pharmacological Group	Musculotropic/Spasmolytic
	Form	Form-5
	Finished product Specifications	Manufacturing specicifcations
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA
	GMP status	M/S Vision: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator [VII]	RRA and Me too not confirmed
	Decision: Deferred for following: **• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** **• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1204.	Name and address of manufacturer / Applicant	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Omega D 3 5mg Injection
	Composition	Each Vial Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 10115 dated 04-03-2019 Rs.50,000/- Dated 01-03-2019 (#0807635)
	Pharmacological Group	Musculotropic/Spasmolytic
	Form	Form-5
	Finished product Specifications	Manufacturing specicifcations
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP status	M/S Vision: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1205.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, 22-23, Industrial triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Examic injection
	Composition	Each 10ml Contains: Tranexamic Acid…1000mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 12440 dated 04-04-2018 Rs.20,000/- Dated 13-03-2018 (#0732783)
	Pharmacological Group	Antifibrinolytic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10 ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Tranexamic Acid Iv Apotex tranexamic acid 1000 mg/10 mL solution for injection vial
	Me-too status	Transolide by GLOBAL is as 1000mg/10 ml
	GMP status	M/S Vision Pharma: GMP Certificate issued on 08.05.2018.
	Remarks of Evaluator VII	
	Decision: Approved	
1206.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	P Caf Tablet 500mg/65mg
	Composition	Each Film Coated Tablet Contains: Paracetamol…500mg Caffeine…65mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0845763)
	Pharmacological Group	Analgesic /Xanthine
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	210 per pack As per SRO
	Approval status of product in Reference Regulatory Authorities	Panadol Extra Advance 500 mg/65 mg Film Coated Tablets by M/s GSK, MHRA Approved.
	Me-too status	Paratol Extra tablet by M/s Highnoon (Reg.# 13346)
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator VII	
	Decision: Deferred for consideration on its turn	
1207.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Fenrate Capsule 200mg
	Composition	Each capsule contains Fenofibrate…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846281)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 200 mg (MHRA approved)
	Me-too status	Corfibrate 200mg Capsule by M/s OBS (Reg.# 073646)
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator VII	In RRA micronized fenofibrate is used
	Decision: Deferred for consideration on its turn	
1208.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Rostatin 10mg Tablet

	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846278)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too status	Rosulin Tablets 10 mg tablet by M/s Highnoon Labs, Reg.# 048372
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	In RRA Rosuvastatin calcium is approved but the applied product is just Rosuvastatin
	Decision: Deferred for consideration on its turn with correction as per reference regulatory authority	
1209.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Rostatin 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13820 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846279)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too status	Rosulin Tablets 10 mg tablet by M/s Highnoon Labs, Reg.# 048372
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	In RRA Rosuvastatin calcium is approved but the applied product is just Rosuvastatin
	Decision: Deferred for consideration on its turn with correction as per reference regulatory authority	
1210.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	C-Pime 1g Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 26376 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each Vial Contains: Cefepime (as hydrochloride) …1000 mg (With L-arginine)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	600/Rs per vial
	Approval Status of Product in Reference Regulatory Authorities.	Cefipime hydrochloride 1gm Injection by M/s Hospira, Inc (USFDA approved)
	Me-too Status	Nuxipim 1g Injection of Bosch

	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	
	Decision: Deferred for the confirmation of manufacturing facility of the applied product (Cephalosporin section)	
1211.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	C-Pime 250mg Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 26370 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each Vial Contains: Cefepime (as hydrochloride) …250 mg (With L-arginine)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's 150 Rs per vial
	Approval Status of Product in Reference Regulatory Authorities.	NA
	Me-too Status	Avetek of Aventek Pharma
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	Evidence of applied formulation in RRA
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **For the confirmation of manufacturing facility of the applied product (Cephalosporin section)**	
1212.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	C-Pime 500 mg Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 26370 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each Vial Contains: Cefepime (as hydrochloride)…250 mg (With L-arginine)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's 339 Rs per vial
	Approval Status of Product in Reference Regulatory Authorities.	MAXIPIME for Injection 500mg Injection by M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Uspime 500mg Injection by Usawa Pharmaceuicals (Reg# 060251)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	
	Decision: Deferred for the confirmation of manufacturing facility of the applied product (Cephalosporin section)	
1213.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Aspam Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 26370 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017

	Composition	Each Vial Contaiins: Phloroglucinol…40mg Trimethyl Phloroglucinol…0.04mg
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's 339 Rs per vial
	Approval Status of Product in Reference Regulatory Authorities.	Cefipime hydrochloride 500mg Injection by M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Uspime 500mg Injection by Usawa Pharmaceuicals (Reg# 060251)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	In RRA Each ampoule contains: Phloroglucinol Dihydrate…40mg Trimethylphloroglucinol…0.04mg
	Decision: Deferred for evidence of approval of applied formulation as "Phloroglucinol" without hydrate in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1214.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Epimate 25mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy. No 26380 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each film coated tablet contains: Topiramate……25mg
	Pharmacological Group	Anti-convulsion
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3x 10's 15.16/ tablet
	Approval Status of Product in Reference Regulatory Authorities.	Topamax Approved in US-FDA
	Me-too Status	Erbro 25mg Tablet of M/s Shawan Pharmaceuticals
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	
	Decision: Approved.	
1215.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Epimate 100 mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 26382 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each film coated tablet contains: Topiramate……100 mg
	Pharmacological Group	Anti-convulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3x10's 28.73/tablet
	Approval Status of Product in Reference Regulatory Authorities.	Topamax (MHRA approved)
	Me-too Status	Tics 100mg tablets of M/s Genix pharma

	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	
	Decision: Approved.	
1216.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Epimate 50 mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 26381 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each film coated tablet contains: Topiramate……50 mg
	Pharmacological Group	Anti-convulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3x10's 22.83/tablet
	Approval Status of Product in Reference Regulatory Authorities.	Topamax (MHRA approved)
	Me-too Status	Erbro 50mg Tablet of M/s Shawan Pharmaceuticals
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	
	Decision: Approved.	
1217.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Aspam 80/80mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 26369 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each sugar-coated tablet contains: Phloroglucinol (dihydrated corresponding to Phloroglucinol)….. ……80mg Trimethylphloroglucinol……80mg
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack Size & Demanded Price	3x10's 493/ pack
	Approval Status of Product in Reference Regulatory Authorities.	Spasfon sugar coated (ANSM) France Approved
	Me-too Status	Spasfon tablet of M/s Himont Pharmaceuticals (Reg.# 018529)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	Firm applied as film coated while the product is approved in France as sugar-coated tablet. On communication revised form 5 along with fee of 5000/- (#1931656) dated 18-7-2019 was provided.
	Decision: Approved with innovator's specification	
1218.	Name and address of manufacturer / Applicant	M/s. Synchro Pharma, 77 Industrial Estate KotLakhpat, Lahore
	Brand Name +Dosage Form + Strength	Duset oral dispersible tablet 4 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14073 dated 7-3-2019 Rs. 20,000 Dated 6-3-2019 (#0800704)
	Composition	Each orodispersible Tablet Contains: Ondansetron as HCL Dihydrate…4mg

	Pharmacological Group	Serotonin 5-HT3 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Zofran tablet of Novartis (MHRA)
	Me-too Status	Zofran tablet of Glaxo lab (020667)
	GMP status	Last GMP inspection Date: 12-6-2019 and 04-7-2019, with acceptable cGMP compliance
	Remarks of the Evaluator.	The firm revised there form 5 and method of manufacturer from orodispersible Tablet Contains: Ondansetron as HCL Dihydrate…4mg to Each film coated Tablet Contains: Ondansetron as HCL Dihydrate…4mg which is according to the reference product with fee of 5000/- (#0800720) dated 11/8/2020
	Decision: Deferred for consideration on its turn	
1219.	Name and address of manufacturer / Applicant	M/s. Synchro Pharma, 77 Industrial Estate KotLakhpat, Lahore
	Brand Name +Dosage Form + Strength	Duset oral dispersible tablet 8 mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 14073 dated 7-3-2019 Rs. 20,000 Dated 6-3-2019 (#0800705)
	Composition	Each orodispersible Tablet Contains: Ondansetron as HCL Dihydrate…8mg
	Pharmacological Group	Serotonin 5-HT3 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Zofran tablet of Novartis (MHRA)
	Me-too Status	Zofran tablet of Glaxo lab (020668)
	GMP status	Last GMP inspection Date: 12-6-2019 and 04-7-2019, with acceptable cGMP compliance
	Remarks of the Evaluator.	The firm revised there form 5 and method of manufacturer from orodispersible Tablet Contains: Ondansetron as HCL Dihydrate… to Each film coated Tablet Contains: Ondansetron as HCL Dihydrate…which is according to the reference product with fee of 5000/- (#0800720) dated 11/8/2020
	Decision: Deferred for consideration on its turn	
1220.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Co-Valstar 160/12.5 Tablets
	Diary No. Date of R& I & fee	Diary No. 315, Date: 10-8-2015, 20,000/-
	Composition	Each film coated tablet contains: Valsartan …160 mg Hydrochlorothiazide….12.5mg
	Pharmacological Group	Anti-hypertensive combination
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's As Per SRO

	Approval status of product in Reference Regulatory Authorities.	Exforge Hct of (USFDA Approved)
	Me-too status	Exforge Hct of M/S Novartis Pharma
	GMP status	Firm has submitted copy of GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
1221.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Vil-Met 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 5897 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846611)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. TGA approved
	Me-too status	GALVUS MET 50MG/850MG TABLETS (Reg # 66106)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1222.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Vil-Met 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5898 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846612)
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET 50/1000 vildagliptin 50 mg/metformin hydrochloride 1000 mg film coated tablet. TGA approved
	Me-too status	Valiant-M Tablets. (Reg No. 0773391)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations

		noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1223.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Tramal SR 100mg Tablet
	Composition	Each film coated sustained release tablet contains: Tramadol Hcl…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5894 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846608)
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMADOL SANDOZ SR tramadol hydrochloride 100mg modified release tablet. TGA approved
	Me-too status	Opadol SR Tablet 100mg by Leads phrma. (Reg No. 065306)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1224.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Rabi Med 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole as Sodium…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5893 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846607)
	Pharmacological Group	Proton Pump Inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rabeprazole 20mg Gastro resistant Tablets of Accord healthcare limited (MHRA approved)
	Me-too status	Rabz 20mg Tablet of M/s Wilshire Pharma (Reg#037482)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance.

		The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	In RRA the tablet is as Rabeprazole 20mg Gastro resistant Tablets but firm applied as enteric coated tablet.
	Decision: Approved with innovator's specification.	
1225.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Ebacin 5mg/5ml Syrup
	Composition	Each 5ml contains: Ebastine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5891 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846605)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	120 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebastel oral solution 1mg/ml of Almirall, Spanish medicine agency
	Me-too status	Olivestin Syrup of M/ Hiranis Karachi (Reg.#076519)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1226.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Ebacin 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5892 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846606)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Kestine 20 mg tablet (Approved in Ireland)
	Me-too status	Antine tablets 20 mg of M/s Wise Pharma (Reg. # 068792)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.

	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1227.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Doxefyl 400mg Tablet
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5890 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846604)
	Pharmacological Group	Systemic drugs for obstructive airway diseases
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	DOXOFILLINA ABC 400 mg uncoated tablet by M/s ABC FARMACEUTICI SpA - Corso Vittorio, AIFA (Italy)
	Me-too status	Profylline tablet 400mg by M/s Kaizen (Reg. # 73744)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1228.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Doxifen 100mg Syrup
	Composition	Each 5ml contains: Doxofylline…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5889 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846603)
	Pharmacological Group	Systemic drugs for obstructive airway diseases
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	60 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Doxofillina ABC 20 mg / ml Syrup by M/s ABC FARMACEUTICI SpA - Corso Vittorio (Italian Medicine Agency (AIFA) Italy
	Me-too status	Profylline Syrup by Kaizen (R. No. 073749)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	

1229.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Levmed 25mg Tablet
	Composition	Each uncoated Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5895 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846609)
	Pharmacological Group	Gastroprokinetic / psychosis / Neuroleptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 25 mg tablet of AIFA italy
	Me-too status	Nauvomit Tablets of M/s Saaaf Pharma (Reg#059377)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1230.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Levmed 50 mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5896 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0846610)
	Pharmacological Group	Gastroprokinetic / psychosis
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl (AIFA Italy Approved).
	Me-too status	Vesulpid Tablets 50mg by M/s Martin Dow Pharmaceutical (Pakistan) Ltd,(Reg#41012)
	GMP status	M/s: Welmed Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1231.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Tegma 80/10 mg Tablet

	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine Besylate…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2051 dated 16-01-2019 Rs.20,000/- Dated 15-01-2019 (#0811381)
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Misar-Am 80/10mg Tablet of M/s Highnoon Pharma (Pvt) Ltd (Reg. # 069151)
	GMP status	GMP inspection dated 12.05.2018, concluded that overall the firm was operating under good level of cGMP.
	Remarks of Evaluator [VII]	As an evidence of bilayer compression machine GMP dated 3-5-2019 is provided in which double layered compression machine is mentioned.
	Decision: Approved	
1232.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Tegma 80/5 mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine Besylate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2050 dated 16-01-2019 Rs.20,000/- Dated 15-01-2019 (#0811394)
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 0669434)
	GMP status	GMP inspection dated 12.05.2018, concluded that overall the firm was operating under good level of cGMP.
	Remarks of Evaluator [VII]	As an evidence of bilayer compression machine GMP dated 3-5-2019 is provided in which double layered compression machine is mentioned.
	Decision: Approved	
1233.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Tegma 40/5 mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine Besylate…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2049 dated 16-01-2019 Rs.20,000/- Dated 15-01-2019 (#0811393)
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/40mg by M/s Mylan Pharms Inc. (USFDA Approved).
	Me-too status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd. Karachi. (Reg. # 066943)
	GMP status	GMP inspection dated 12.05.2018, concluded that overall the firm was operating under good level of cGMP.
	Remarks of Evaluator [VII]	As an evidence of bilayer compression machine GMP dated 3-5-2019 is provided in which double layered compression machine is mentioned.
	Decision: Approved	
1234.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amicell 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6530 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811873)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1x 10, 3x10's, 6x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet (Reg# 76060)
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved	
1235.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lacos 50mg Tablet
	Composition	Each film coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6527 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0841082)
	Pharmacological Group	Anticonvulsant
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1x14,28's As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat oral tablet of UCB Inc, USFDA Approved.
	Me-too status	Atcomid 50mg tablet of M/s Atco Pharma (Reg. # 075947).
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1236.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Sirbin 125mg Tablet

	Composition	Each Tablet Contains: Terbinafine as HCL…125mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6524 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811867)
	Pharmacological Group	Antifungals for systemic use
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMISIL terbinafine 125mg (uncoated tablets) TGA Approved.
	Me-too status	"Terbizine Tablet of M/s Candid Pharma Lalap tablet of Hilton pharma (Reg # 070118)
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	In RRA it is approved as Terbinafine HCl eq. to Terbinafine…125mg" in uncoated form but firm applied as Terbinafine HCl film coating tablet. On communication firm rectify the form 5 and formulation without fee
	Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product.	
1237.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Sidone 40mg Capsule
	Composition	Each Capsule Contains: Ziprasidone HCL…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6526 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811869)
	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10,2x7,3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	GEODON®(ziprasidone HCl) capsules USFDA Approved
	Me-too status	Zopeka 40mg Capsule M/s Barret Hodgson, Karachi (Reg # 079550)
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	In RRA it is approved as Ziprasidone as HCl but firm applied as Ziprasidone HCl. On communication firm claimed that it's typographical mistake and rectify the form 5 and formulation without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product.	
1238.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fasgin 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…50mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 6533 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811876)
	Pharmacological Group	Other antiepileptic's
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamotrigine Accord 50 mg uncoated Tablets (MHRA approved)
	Me-too status	Epictal 50mg Tablet of M/s Bosch
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved	
1239.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Deact 500mg Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 26379 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each Vial Contains: Cefoperazone Sodium…250mg Sulbactum Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	141 Rs/ vial
	Approval Status of Product in Reference Regulatory Authorities.	PMDA, Japan Approved
	Me-too Status	2- Sum 500mg injection of M/s Sami Pharma FOPERA of Jawa pharma(Reg. # 079941)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML.
	Remarks of the Evaluator.	
	Decision: Deferred for the confirmation of manufacturing facility of the applied product (Cephalosporin section)	
1240.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Cephdine 250 mg capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 26370 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each capsule contains: Cephradine monohydrate eq to cephradine ….250 mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10.33/Rs per 2x6
	Approval Status of Product in Reference Regulatory Authorities.	Cefradine 500mg Capsules by Athlone Pharmaceuticals (MHRA Approved)
	Me-too Status	Dinar 500mg capsule by Baxter Pharma
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML.
	Remarks of the Evaluator.	Firm revised its formulation from cephradine to Cephradine monohydrate eq to cephradine as per RRA with fee of 5000/-

		(#0322077) dated 21-7-2019 was provided.
	Decision: Approved	
1241.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Cephdine 500mg capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 26371 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each capsule contains: Cephradine monohydrate eq to cephradine ….500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20.3 per capsule 2x6
	Approval Status of Product in Reference Regulatory Authorities.	Cefradine 500mg Capsules by Athlone Pharmaceuticals (MHRA Approved)
	Me-too Status	Dinar 500mg capsule by Baxter Pharma
	GMP status	Last GMP inspection Date: 9-10-2017, with Satisfactory cGMP compliance but ceph section is not truly dedicated.
	Remarks of the Evaluator.	Firm revised its formulation from cephradine to Cephradine monohydrate eq to cephradine as per RRA with fee of 5000/- (#0322076) dated 21-7-2019 was provided.
	Decision: Approved	
1242.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Cephdine 250mg/5ml Suspension
	Diary No. Date of R& I & fee	Form-5 Dy.No 26373 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each 5ml contains: Cephradine monohydrate eq to cephradine ……250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	141 Rs/ vial
	Approval Status of Product in Reference Regulatory Authorities.	Cefradine 250mg/5ml dry powder for syrup by M/s Strides Pharma UK Ltd (MHRA Approved)
	Me-too Status	Licef Dry Powder suspension 250mg/5ml by M/s Wisdom Pharmaceuticals (Reg#078531)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	In form 5, capsule is mentioned instead of suspension. Firm claimed that it's a typographical error and fee of 5000/- (#0322078) dated 21-7-2019 was provided.
	Decision: Approved	
1243.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Citin 100mg/ml Syrup
	Diary No. Date of R& I & fee	Form-5 Dy.No 26374 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each ml Contains: Citicoline (as Sodium)…. …100mg
	Pharmacological Group	Psychostimulants and nootropics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack Size & Demanded Price	600/ per 30 ml

		1100 per 60 ml
	Approval Status of Product in Reference Regulatory Authorities.	Citicolina Ferrer 100mg/ml Solucion Oral EFG by M/s Ferrer Internacional,S.A (Spain Approved)
	Me-too Status	Citolin Syrup by M/s Global Pharmaceuticals (Reg#029540)
	GMP status	Last GMP inspection Date: 18-02-2020, panel recommend renewal of DML
	Remarks of the Evaluator.	Firm revised its formulation from Citicolineto Citicoline (as Sodium) as per RRA with fee of 5000/- (#0322079) dated 21-7-2019 was provided.
	Decision: Approved with innovator's specification.	
1244.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Feno-Med 67mg Capsule
	Composition	Each Capsule Contains: Fenofibrate(Micronized)…67mg
	Diary No. Date of R& I & fee	(Duplication) Form-5 Dy.No 8324 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0836151)
	Pharmacological Group	Lipid modifying agent
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Fenoget 67mg micronized capsules of M/s Getz Pharma (Reg. # 047197)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Physical form of API was not mentioned on communication firm revised there form 5 with 5000/- fee (#2012042) dated 10-6-2020
	Decision: Approved	
1245.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Feno-Med 200 mg Capsule
	Composition	Each Capsule Contains: Fenofibrate…200 mg
	Diary No. Date of R& I & fee	(Duplication) Form-5 Dy.No 8331 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0836152)
	Pharmacological Group	Lipid modifying agent
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate (Micronized) USFDA
	Me-too status	Fenoget 200mg micronized capsules of M/s Getz Pharma (Reg. # 047198))
	GMP status	M/S Mediate Pharma

		Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Physical form of API was not mentioned on communication firm revised there form 5 with 5000/- fee (#2012041) dated 10-6-2020
	Decision: Approved	
1246.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Medinafine 250mg Tablet
	Composition	Each Tablet Contains: terbinafine hydrochloride, equivalent to terbinafine …250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8328 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0818181)
	Pharmacological Group	Antifungal
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s Novartis Pharmaceuticals Uk Limited, MHRA Approved.
	Me-too status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Film coating is mentioned in master formulation but in RRA it is approved as uncoated. Firm revised its formulation and form 5 as uncoated tablet with fee of 5000/- (#2012044) dated 16 june 2020
	Decision: Approved	
1247.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Medinafine 125 mg Tablet
	Composition	Each Tablet Contains: terbinafine hydrochloride, equivalent to terbinafine …125 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8323 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Antifungal
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMISIL terbinafine 125mg (uncoated tablets) TGA Approved.
	Me-too status	"Terbizine Tablet Candid Pharmaceuticals Reg No. 070118
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines

	Remarks of Evaluator [VII]	Film coating is mentioned in master formulation but in RRA it is approved as uncoated. Firm revised its formulation and form 5 as uncoated tablet with fee of 5000/- (#2012043) dated 16 june 2020
	Decision: Approved	

b. Deferred cases

1248.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Irbesar Tablet 150 mg
	Composition	Each film coated tablet contains: Irbesartan … 150 mg
	Diary No. Date of R& I & fee	D#15716, 20-9-2017; Rs. 20,000/- (Slip# 0614799)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 14,20,28, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan 150 mg Film coated tablet by Accord Healthcare Limited, UK (MHRA approved)
	Me-too status	Gooday 150 mg by Wilson's
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	Firm revise their formulation as film coated tablet without submission of fee.
	Decision of 295: Deferred for submission of fee for revision of formulation from uncoated tablet to film coated tablet. Remarks of evaluator: Firm revise their formulation as film coated tablet by submission of fee of Rs. 5000/- (#1983752) dated 10-6-2020 **Decision: Approved.**	
1249.	Name and address of manufacturer / Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dyonate 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Ibandronic Acid as ibandronic sodium monohydrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5832 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519167)
	Pharmacological Group	Bisphosphonate
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA

	GMP status	M/S Dynatis Pharma Last GMP inspection report d ated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	Evidence of me too and RRA
	Decision of 295: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board Remarks of evaluator: RRA: Bondronat 50 mg film-coated tablets (MHRA) Me too: Bondronat Tablets by hoffman La roch (#043008) **Decision: Approved with innovator's specification.**	
1250.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cilasten 500mg IV Injection
	Composition	Each Vial Contains: Imipenem as monohydrate…500mg Cilastatin as Sodium…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38581 dated 23-11-2018 Rs.50,000/- Dated 23-11-2018 (# 0811002)
	Pharmacological Group	Beta-lactam antibacterial
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Imipenem/Cilastatin 500 mg/500 mg, powder for solution for infusion by M/s Fresenius Kabi. (MHRA Approved)
	Me-too status	Cilapen 500mg injection by M/s Bosch (Reg. # 048491)
	GMP status	Last GMP inspection was conducted on 03/08/18 Conclusion: "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule (Cephalosporin) 2- Dry suspension section (Cephalosporin) 3- Dry powder Injectable section (Cephalosporin) 4- Dry powder Injectable section (Carbapenems)"
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of already contract manufactured products. Remarks of evaluator Firm state that they don't have any product being manufactured by contract as of 3-2-2020 **Decision:** **Deferred for capacity assessment of M/s Nicholas Pharmaceuticals.**	
1251.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Neopenem 500 mg IV Injection

	Composition	Each Vial Contains: Meropenem as Trihydrate …500 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38582 dated 23-11-2018 Rs.50,000/- Dated 23-11-2018 (# 0811004)
	Pharmacological Group	Carbapenems
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Meronem IV 500 mg Powder for solution for injection by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Olver Injection by M/s Genix Karachi (Reg.# 080605)
	GMP status	Last GMP inspection was conducted on 03/08/18 Conclusion: "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule (Cephalosporin) 2- Dry suspension section (Cephalosporin) 3- Dry powder Injectable section (Cephalosporin) 4- Dry powder Injectable section (Carbapenems)"
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of already contract manufactured products. Remarks of evaluator Firm state that they don't have any product being manufactured by contract as of 3-2-2020 **Decision: Deferred for capacity assessment of M/s Nicholas Pharmaceuticals.**	
1252.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Neopenem 1g IV Injection
	Composition	Composition Each Vial Contains: Meropenem as Trihydrate …1gm Diary No. Date of R& I & fee
	Diary No. Date of R& I & fee	Form-5 Dy.No 38583 dated 23-11-2018 Rs.50,000/- Dated 23-11-2018 (# 0811006)
	Pharmacological Group	Carbapenems
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Meronem IV 1g Powder for solution for injection by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Penro 1000mg Injection IV by M/s Bosch (Reg. # 042107)
	GMP status	Last GMP inspection was conducted on 03/08/18 Conclusion: "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule (Cephalosporin) 2- Dry suspension section (Cephalosporin) 3- Dry powder Injectable section (Cephalosporin)

		4- Dry powder Injectable section (Carbapenems)"
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of already contract manufactured products. Remarks of evaluator Firm state that they don't have any product being manufactured by contract as of 3-2-2020 **Decision: Deferred for capacity assessment of M/s Nicholas Pharmaceuticals.**	
1253.	Name and address of manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	Novocrom 4%w/v ophthalmic solution
	Diary No. Date of R& I & fee	Form-5 Dy.No 13676 dated 7-3-2019 Rs.20,000/- Dated 7-3-2019 (Slip#1900338)
	Composition	Each ml ophthalmic solution contains: - Sodium Cromoglicate …. 40 mg
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	15- and 10-ml polyethylene bottle As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA Cromosol Eye Drops 4% M/S polyfine (#032455) Deferred in 292
	GMP status	Panel inspection conducted on 12-02-2019 & 21-02-2019, and the report concludes that the panel unanimously Recommended M/s Novex Pharmaceuticals for the grant of DML
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in same strength and volume in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for following: •Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm •Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board Remarks of evaluator Firm provided the following RRA: Cromolyn sodium 4% ophthalmic solution (USFDA) Me too: Sodium Cromoglycate 4% W/V (# 013156) **Decision: Approved with innovator's specification.**	
1254.	Name and address of manufacturer / Applicant	M/s Elite Pharma Pvt Ltd., P.D.H. Street 9.5 km Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Gentalite 80 mg/2 ml injection
	Composition	Each 2 ml contains: Gentamicin sulfate equivalent to Gentamicin…….80 mg
	Diary No. Date of R& I & fee	Dy.No. 11923, 15-8-2017, Rs.20,000/=
	Pharmacological Group	Aminoglycoside Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2ml x 5's 2ml x 25's/

		As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidomycin 80mg/2ml Solution for Injection by M/s Aventis Pharma Limited, MHRA Approved.
	Me-too status	DBL Gentamicin 80mg/2ml injection
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes: "It is advised to overcome the shortcomings and submit the compliance report to the competent authorities so that the inspection could be conducted accordingly."
	Remarks of Evaluator	Show cause notice dated 11 Nov 2019 for the Suspension of production in all sections was issued.
	Decision 293: Registration Board referred the case to QA & LT Division for updated GMP status of the firm. Remarks of evaluator Firm provided the resumption of production order in liquid injectable ampoule and semi-solid (cream, ointment section only) dated 27 Dec 2019. **Decision: Approved with innovator's specification.**	
1255.	Name and address of manufacturer / Applicant	M/s Elite Pharma Pvt Ltd., P.D.H. Street 9.5 km Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Betavel ointment 5 gm Tube
	Composition	Each 5 gm ointment Contains: Betamethasone as valerate……..0.1%
	Diary No. Date of R& I & fee	Dy.No. 11922, 15-8-2017, Rs.20,000/=
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	Unit price, 12/-
	Approval status of product in Reference Regulatory Authorities.	BETA-VAL 0.1% ointment (USFDA)
	Me-too status	Betacin of Geofman Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes: "It is advised to overcome the shortcomings and submit the compliance report to the competent authorities so that the inspection could be conducted accordingly."
	Remarks of Evaluator	Show cause notice dated 11 Nov 2019 for the Suspension of production in all sections was issued.
	Decision 293: Registration Board referred the case to QA & LT Division for updated GMP status of the firm. Remarks of evaluator Firm provided the resumption of production order in liquid injectable ampoule and semi-solid (cream, ointment section only) dated 27 Dec 2019. **Decision: Approved**	
1256.	Name and address of manufacturer / Applicant	M/S Welwrd Pharmaceuticals, Plot No; 3, Block A, Phase I– II, Industrial Estat, Hattar, Pakistan Contract manufacturing from M/s WinBrains Research Laboratories, Plot # 69/1, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Top-Dex eye drops
	Diary No. Date of R& I & fee	Form-5 Dy. No 26337 dated 28-12-2017 Rs. 50,000 Dated 28-12-2017
	Composition	Each Drop Tainer Dispenser Contains: Dexamethasone…… 0.1% Tobramycin ……0.3%
	Pharmacological Group	Corticosteroids and Aminoglycoside antibiotic

	Type of Form	Form-5
	Finished Product Specification	USP (ophthalmic suspension)
	Pack Size & Demanded Price	5ml As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	TOBRADEX by Novartis (USFDA Approved)
	Me-too Status	TOBRADEX by Novartis
	GMP status	M/S Winsbrain GMP Certificate of GMP, Date: 20-5-2019 (Have eye drop general section)
	Remarks of Evaluator VII	Sections of welward: 8 Products on contract manufacturing: 4 (2 approved letter awaited) Clarification shall be submitted whether applied formulation is in solution form or suspension form, since reference product approved by USFDA is in suspension dosage form. Confirmation of container closure system whether as per innovator or otherwise and confirmation of manufacturing facility of Drop Tainer Dispenser
	Decision 293: Deferred for clarification of dosage form i.e. solution or suspension Remarks of evaluator Firm revised the formulation with 20,000 fee (#2028796) dated 06/07/2020 to Each ml suspension Contains: Dexamethasone…… 0.1% Tobramycin …….0.3%	
	Decision: Deferred for confirmation of separate dispensing booth for steroidal ingredients.	
1257.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Brand Name+ Dosage Form+ Strength	Imuvir 500 mg Injection
	Composition	Each vial contains: Ganciclovir sodium equavent to Ganciclovir…….500 mg (Lyophylized in container)
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, originally received at 30-12-2014, Rs.Rs.20,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Antiviral (Nucleoside analogue)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer‟s Specification
	Pack Size & Demanded Price	1‟s As per SRO
	Approval status of product in Reference Regulatory Authorities	CYTOVENE-IV (USFDA) in a vile
	Me-too status	Ciganclor freeze dried for injection (Reg#047562)
	GMP status	Last inspection report dated 02-08-2018 concluded that M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of Evaluator VII	No of contract manufactured products:29
	Decision of 293: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Remarks of evaluator VII The Firm responded that as the innovators product cymevene IV is as sterile lyophilized powder so their product is also in sterile lyophilized powder form. Approval of lyophilized vial section was also provided. Remarks:	

	Firm replied that the applied dosage form is by lyophilization and we are not using ready to fill prelyophilized powder. **Decision: Approved with innovator's specification.**	
1258.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine as besylate Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 7998 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0847614)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Misar-Am 80/10mg Tablet of M/s Highnoon Pharma (Pvt) Ltd (Reg. # 069151)
	GMP status	Same As Above
	Remarks of Evaluator VII	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision of 295: Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. Remarks of evaluator VII The Firm submitted the Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. **Decision: Approved with innovator's specification.**	
1259.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 40mg/10mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine as besylate Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7397 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0847613)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/40mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Amtas 10mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 066945)
	GMP status	Same As Above
	Remarks of Evaluator VII	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.

	Decision of 295: Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. Remarks of evaluator VII The Firm submitted the Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. **Decision: Approved with innovator's specification.**	
1260.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine as besylate Amlodipine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 7953 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0548110)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 0669434)
	GMP status	Same As Above
	Remarks of Evaluator VII	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision of 295: Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. Remarks of evaluator VII The Firm submitted the Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. **Decision: Approved with innovator's specification.**	
1261.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 40mg/5mg
	Composition	Each bilayer Tablet Contains: Telmisartan…40mg Amlodipine as besylate Amlodipine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7396 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0798433)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/40mg by M/s Mylan Pharms Inc. (USFDA Approved).
	Me-too status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd Karachi. (Reg. # 066943)
	GMP status	Same As Above
	Remarks of Evaluator VII	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the

		invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision of 295: Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. Remarks of evaluator VII The Firm submitted the Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. **Decision: Approved with innovator's specification.**	
1262.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart H Tablets 40mg/12.5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7399 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0798432)
	Pharmacological Group	Antihypertensive (Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Same As Above
	Remarks of Evaluator VII	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision of 295: Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. Remarks of evaluator VII The Firm submitted the Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine. **Decision: Approved with innovator's specification.**	
1263.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Doxo Tablet 400mg
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7016 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0830203)
	Pharmacological Group	Systemic drugs for obstructive airway diseases
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	DOXOFILLINA ABC 400 mg uncoated tablet by M/s ABC FARMACEUTICI SpA - Corso Vittorio, AIFA (Italy)
	Me-too status	Profylline tablet 400mg by M/s Kaizen, Reg no. Antine tablets 20 mg of M/s Wise Pharma (Reg. # 73744)
	GMP status	Same As Above

	Remarks of Evaluator [VII]	In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet in form 5. Upon communication of above observations firm has submitted that our applied formulation is uncoated as there is no coating material in method of manufacturing but typographically we mentioned film coated in form 5 were attached BMR is of uncoated tablet.
	Decision of 295: Deferred for submission of fee for revision of formulation. Remarks of evaluator VII The Firm submitted the fee of 5000/- (#2036781) dated 21-08-2020 for revision of formulation from film coated tablet to uncoated tablet. **Decision: Approved with innovator's specification.**	
1264.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro DS 40mg/5ml Oral Suspension
	Composition	Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1692 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0801948)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50, 75, 100 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40 mg/5 ml oral by Aurobindo pharma (MHRA)
	Me-too status	Prelox of Bosch Pharma
	GMP status	As per last inspection report dated 08/03/2019, Same as Above.
	Remarks of Evaluator [VII]	In RRA it is approved as granules for suspension
	Decision of 295: Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is granules for suspension need detail outline of granulation process. Remarks of evaluator VII The Firm submitted the manufacturing method and BMR with detail outline of granulation process in line with RRA. **Decision: Approved with innovator's specification.**	
1265.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals., Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name +Dosage Form+ Strength	Thiocol capsule 4 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5059E dated 7-6-2017 Rs 20,000/- Dated 2-6-2017 (Slip#0608270)
	Composition	Each Capsule Contains: Thiocolchicoside as sustained release pellets eq Thiocolchicoside…4mg
	Pharmacological Group	Muscle relaxant
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Myoplege 4mg capsule France (ANSM approved)
	Me-too status	Ezoside capsule 4mg of M/s Akhai Pharma (Reg. # 070427)
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.

	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed as sustained release pellets. If indeed applied as pellets then source of pellets is required to be submitted. Letter issued on24th Dec 2019
	Decision of 293: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Remarks of evaluator VII Firm submit the revised dossier for Each capsule contains Thiocolchicoside …4mg (Without fee) RRA: Myoplege 4mg capsule France (ANSM approved) Me to: Ezoside capsule 4mg of M/s Akhai Pharma (Reg. # 070427) Decision of 295: Deferred for submission of requisite fee for revision of formulation from Each Capsule Contains: Thiocolchicoside as sustained release pellets eq Thiocolchicoside…4mg to each capsule contain Thiocolchicoside …4mg Remarks of evaluator VII Firm again provided the revised form 5 with the copy of original 20,000/- fee. No fee of 5000/- was submitted for revision of formulation. **Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product.**	
1266.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunol Tablets 80/80mg
	Composition	Each sugar-coated tablet contains: Phloroglucinol…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Form-5 Dy. No 3478 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0810185)
	Pharmacological Group	Antispasmodic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasfon sugar- coated tablet by M/s Teva Health (ANSM) France Approved
	Me-too status	Anafortan Plus Tablets Each sugar-coated tablet of M/s Ali Gohar (Reg.# 024504)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator VII	In ANSM it is approved as anhydrous phloroglucinol 62.233 mg in the form of: hydrated phloroglucinol 80 mg but firm applied as phloroglucinol 80 mg.
	Decision of 295: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation. Remarks of evaluator VII	

	In ANSM it is approved as anhydrous phloroglucinol 62.233 mg in the form of: hydrated phloroglucinol 80 mg but firm applied as phloroglucinol 80 mg. Firm clarify that "there is a typographical mistake that only phloroglucinol is mentioned this must be phoroglucinol dihydrate please considered this as phloroglucinol dihydrate instead of phloroglucinol. Fee of 5000/- (2034909) dated 4- sep 2020. **Decision: Approved with innovator's specification.**	
1267.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunol Injection 40/0.04mg
	Composition	Each 4ml contains: Dihydrated Phloroglucinol…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3477 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0810186)
	Pharmacological Group	Antispasmodic.
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	4 ml in glass ampoule 6 and 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	In ANSM it is approved as anhydrous phloroglucinol 31.12 mg in the form of: phloroglucinol dihydrate but firm applied as Dihydrated Phloroglucinol…40mg
	Decision of 295: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation. Remarks of evaluator VII The Firm submitted that "Our formulation initiall y submitted is phloroglucinol dihydrate not just phloroglucinol which is according to innovators". But the original query was that in ANSM it is approved as anhydrous phloroglucinol 31.12 mg in the form of: phloroglucinol dihydrate not just phloroglucinol dihydrate. Firm also provided the revised master formulation with the copy of original fee of 5000/- (2034908) dated 4 sep 2020 was submitted for revision of formulation. **Decision: Approved with innovator's specification.**	

Case No. 03 Registration applications for local manufacturing of (veterinary) drugs
b. Deferred Cases

1268.	Name and address of manufacturer / Applicant	M/s Aptly pharmaceuticals, 5 Km, Sargodha road Bypass, Faisalabad
	Brand Name +Dosage Form + Strength	Aoromox-C Powder
	Diary No. Date of R& I & fee	Dy.No.29875, 5-9-18, Rs. 20,000/-
	Composition	Each gm contains Amoxicillin (base)....100 mg Colistin sulphat …500,000IU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer

	Pack size & Demanded Price	500 gm, 1 kg, 2.5 kg, 5 kg Decontrolled
	Me-too status	Colimoxin Powder. (034583)
	GMP status	Last GMP Inspection Conducted on 6 August 2018 with conclusive remarks of good compliance for grant of drug manufacturer license by way of formulation in respect to following sections • Oral liquid General • Oral liquid antibiotic • Oral powder general • Oral powder antibiotic • Oral powder penicillin
	Remarks of the Evaluator.	
	Decision 293: Deferred for verification of composition of applied formulation. Remarks of evaluator Colimoxin Powder of Salmore Pharma (Me too) is same as the applied formulation **Decision: Approved with innovator's specification.**	
1269.	Name and address of manufacturer / Applicant	M/s Aptly pharmaceuticals, 5 Km, Sargodha road Bypass, Faisalabad
	Brand Name +Dosage Form + Strength	Gut treat plus Powder
	Diary No. Date of R& I & fee	Dy.No.29923, 5-9-18, Rs. 20,000/-
	Composition	Each kg contains Procaine penicillin....12 gm Streptomycin sulphate…...36 gm Zinc bacitracin….. 52 gm Colistin sulphate…. 60 MIU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	500 gm, 1 kg, 2.5 kg, 5 kg Decontrolled
	Me-too status	Pro Sb-Plus Powder (028508)
	GMP status	Last GMP Inspection Conducted on 6 August 2018 with conclusive remarks of good compliance for grant of drug manufacturer license by way of formulation in respect to following sections • Oral liquid General • Oral liquid antibiotic • Oral powder general • Oral powder antibiotic • Oral powder penicillin
	Decision 293: Deferred for verification of composition of applied formulation. Remarks of evaluator Pro Sb-Plus Powder (028508) of Medicure Lab (Me too) is same as the applied formulation **Decision: Approved with innovator's specification.**	

Case No. 04 Registration applications of categories to be considered on priority

Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

b. Export facilitation

Following cases of M/s Tabros Pharma Pvt Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi were received from PR-I/EFD vide letter No. F. 1-6/2019-PR.I (EFD) dated 17th August, 2020. According to the contents of the letter the firm has claimed 3 molecules to be considered on priority against export worth USD 875,668.61/- which is duly verified from submitted documents (Form E GD and shipment invoices) as per the decision of Registration Board.		
1270.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Linzoy Topical Gel 1.5%
	Composition	Each gram contains: Clindamycin as Phosphate…1% Hydrous Benzoyl Peroxide eq.to anhydrous Benzoyl Peroxide …5%
	Diary No. Date of R& I & fee	Form-5 Dy. No 16055 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antibacterial
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Duac Once Daily 10 mg/g + 50 mg/g Gel (Approved in MHRA)
	Me-too status	Benclin Gel of M/s Elko Org. (Pvt), Ltd. 061908
	GMP status	Last inspection report 07/02/18, On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of evaluator [VII]	In RRA the reference product contains Anhydrous Benzoyl Peroxide eq.to Hydrous Benzoyl Peroxide but firm applied as Benzoyl peroxide on communication the firm revised their formulation from Benzoyl peroxide to Anhydrous Benzoyl Peroxide eq.to Hydrous Benzoyl Peroxide with fee of 5000/- (# 1991807) dated 26 aug 2020
	Decision: Approved with innovator's specification.	
1271.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cutis Spray 1%
	Composition	Each 1 spray solution contains: Terbinafine Hcl…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16051 dated 07-03-2019 Rs.20,000/- (#0842622) Dated 07-03-2019
	Pharmacological Group	Antifungal
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamisil® AT 1% Spray by M/s GSK UK (MHRA Approved)
	Me-too status	Lamisil spray by M/s Novartis Pharma (Reg # 021173)

	GMP status	Last inspection report 07/02/18, On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of evaluator [VII]	
	Decision: Approved with innovator's specification.	
1272.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fusil 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Sodium Fusidate…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 16054 dated 07-03-2019 Rs.20,000/- (#0842625) Dated 06-03-2019
	Pharmacological Group	Anti-infective
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin 250 mg Tablets of MHRA approved
	Me-too status	Pandate 250mg Tablets, film-coated. (Reg. No. 81426)
	GMP status	Last inspection report 07/02/18, On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of evaluator [VII]	
	Decision: Approved with innovator's specification.	
Following cases of were received from PR-I/EFD vide letter No. F. 1-6/2019-PR.I (EFD) dated 17th August, 2020. According to the contents of the letter the firm has claimed 3 molecules to be considered on priority against export worth USD 102,656.27/- which is duly verified from submitted documents (Form E GD and shipment invoices) as per the decision of Registration Board.		
1273.	Name and address of manufacturer / Applicant	M/s Efroze Chemical Industries Pvt Ltd. 146/23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Efnor 0.75mg Tablet
	Composition	Each Tablet Contains: Levonorgestrel…0.75mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11399 dated 05-03-2019 Rs.20,000/- (# 082817) Dated 05-03-2019
	Pharmacological Group	Hormonal contraceptives for systemic use
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PLAN B (**LEVONORGESTREL**) by Duramed (USFDA)
	Me-too status	Emkit (**LEVONORGESTREL**) by Zafa Pharmaceutical
	GMP status	Last inspection report 19-3-2018, panel recommends the grant of renewal of the DML by way of formulation
	Remarks of evaluator [VII]	
	Decision: Deferred for confirmation of segregated facility from Licensing Division DRAP	

1274.	Name and address of manufacturer / Applicant	M/s Efroze Chemical Industries Pvt Ltd. 146/23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Gynacept 5mg Tablet
	Composition	Each Tablet Contains: Norethisterone …5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11398 dated 05-03-2019 Rs.20,000/- (#0812819) Dated 05-03-2019
	Pharmacological Group	Progestogen
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Primolut N of MHRA approved
	Me-too status	Postpon-M Tablet by M/s OBS, (Reg# 073532)
	GMP status	Last inspection report 19-3-2018, panel recommends the grant of renewal of the DML by way of formulation
	Remarks of evaluator [VII]	Steroidal hormone section is required (Tablet hormone section present) Firm request change in brand name to "Gynacept tablet 0.75"
	Decision: Deferred for confirmation of segregated facility from Licensing Division DRAP	
1275.	Following cases of M/s S.J & G Fazul Ellahie were received from PR-I/EFD vide letter No. F. 1-6/2019-PR.I (EFD) dated 17th August, 2020. According to the contents of the letter the firm has claimed 3 molecule to be considered on priority against export worth USD 104,097/- which is duly verified from submitted documents (Form E GD and shipment invoices) as per the decision of Registration Board.	
1276.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Mega Gold Powder
	Composition	Each Kg Contains: Vitamin A...0.8gm Vitamin D3...0.16gm Vitamin E...0.38gm Vitamin B1...1gm Vitamin B2...1.25gm Vitamin B12...0.001gm Vitamin B3...6.25gm Vitamin B6...4gm Copper Sulphate...0.25gm Magnesium Sulphate...25gm Calcium Chloride...0.023gm Zinc Sulphate...2.17gm Manganese Sulphate...10gm Potassium Iodide...0.5gm Sodium Selenite...0.01gm D.C.P (Phosphorous)...150gm Sodium Chloride...120gm
	Diary No. Date of R& I & fee	Form-5 Dy.No 27388 dated 17-12-2019 Rs.20,000/- (#1953791) Dated 16-12-2019
	Pharmacological Group	Nutritional supplement
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO

	Me-too status	WHITE GOLD POWDER by Leads Pharma (#'058842)
	GMP status	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
	Remarks of evaluator [VII]	
	Decision: Approved with innovator's specification and change of brand name.	
1277.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Trisulf Powder
	Composition	Each gm Contains: Trimethoprim…80mg Sulphadiazine Sodium…420mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 27387 dated 17-12-2019 Rs.20,000/- (# 1936350) Dated 16-12-2019
	Pharmacological Group	Dihydrofolate reductase inhibitor and sulfonamide antibacterial
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Me-too status	NA
	GMP status	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
	Remarks of evaluator [VII]	DRAP me too evidence needed provided reference of cotrim powder (#049295) of prix can't be verified from data base
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	

Case No. 05 Registration applications of import cases

1278.	Name and address of Applicant	M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt
	Detail of Drug Sale License	Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan Validity: 7-April- 2020 Status: License to sell drug as distributor
	Name and address of manufacturer	Vem ilac San. Ve Tic. A.S. Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mahallesi. Fatih Bulvari. No 38 Kapakli/TEKIRDAG/Turkey
	Name and address of marketing authorization holder	Vem ilac San. Ve Tic. A.S. Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mah. Fatih Blv. No 38 Kapakli/TEKIRDAG/Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.14613 Dated 19-01-2018
	Fee including differential fee	Rs. 50,000/- Dated 19-04-2018
	Brand Name +Dosage Form + Strength	Blumet I.V Solution for injection 50 mg/ 5ml
	Composition	Each 1 ml solution contain Methylene Blue…. 10 mg
	Finished Product Specification	In-house
	Pharmacological Group	Antidotes; Other diagnostic agents
	Shelf life	36 Months
	Demanded Price	NA

	Pack size	5 ml glass ampoule of Type 1
	International availability	NA
	Me-too status	NA
	Detail of certificates attached	COPP (Original, Embassy Attested) Certificate No:2018/15g6 Certifying Authority: Ministry of health Turkish medicine and medical devise agency Valid Date:25-4-2020 Letter of Authorization (original) Date of Agreement:7-06-2018 (Valid for 5 year) Free sale (Original, Embassy Attested) Certificate No:2018/1581 Certifying Authority: Ministry of health Turkish medicine and medical devise agency Valid Date:24-4-2020
	Remarks of the Evaluator [VII]	• Stability is at 45°C ± 2°C / 75% ± 5% RH (6 months) and 30°C ± 2°C / 65% ± 5% RH (6 months) for 3 batches is provided. (Stability starting date: 11-7-2016) • Evidence of approval of applied formulation in reference regulatory authorities not available. PROVAYBLUE 5 mg/ ml (50 mg/ 10 ml) (USFDA) is in different strength and provided label of 10 mg/ml itself claimed this drug is not found to be effective and safe by USFDA and this label is not approved by FDA.

Decision 288:

Deferred for following:

- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
- Long term Stability study covering the shelf life of applied product under the conditions of zone IV-A.

Remarks of evaluator [VII]:

- Firm has provided Stability study Real time: 30°C ± 2°C / 75% ± 5% RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months

S. NO	Remarks	Response
1.	Evidence of approval of applied formulation in RRA is not valid as reference of Cambodia, Korea and Vietnam was provided by the firm.	Reference of MHRA is provided again but it can not be confirmed from the official site

Decision: Deferred for following:

• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting and DSL status as expired on 7th April 2020.

1279.	Name and address of Applicant	M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt
	Detail of Drug Sale License	Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan Validity: 7-April- 2020 Status: License to sell drug as distributor
	Name and address of manufacturer	Vem ilac San. Ve Tic. A.S. Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mah. Fatih Blv. No 38 Kapakli/TEKIRDAG/Turkey

	Name and address of marketing authorization holder	Vem ilac San. Ve Tic. A.S. Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mahallesi. Fatih Bulvari. No 38 Kapakli/TEKIRDAG/Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.14610 Dated 19-01-2018
	Fee including differential fee	Rs. 50,000/- Dated 19-04-2018
	Brand Name +Dosage Form + Strength	Fuxesin 100 mg injection
	Composition	Each vial contains Anidulafungin…. 100 mg (Lyophilized powder for solution for infusion)
	Finished Product Specification	In-house
	Pharmacological Group	Antifungal
	Shelf life	24 Months (2-8 ºC)
	Demanded Price	As per SRO
	Pack size	20 ml, 50 ml, 100 ml Clear glass vial Type-I
	International availability	Ecalta 100 milligram(s) Powder and solvent for solution for infusion Pfizer Europe (MHRA)
	Me-too status	NA
	Detail of certificates attached	COPP (Original, Embassy Attested) Certificate No:2018/1086 Certifying Authority: Ministry of health Turkish medicine and medical devise agency Valid Date:20-3-2020 Letter of Authorization (Original) Date of Agreement:1-01-2016 (Valid for 5 year) Free sale (Original, Embassy Attested) Certificate No:2018/1568 Certifying Authority: Ministry of health Turkish medicine and medical devise agency Valid Date:24-4-2020
	Remarks of the Evaluator [VII]	• Stability is at 5°C ± 3°C (24 months) and 25°C ± 2°C / 60% ± 5% RH (for 3 batches) • Innovator, ERAXIS for Injection un reconstituted vials and companion diluent vials should be stored at 2-8ºC; Excursions for 96 hours up to 25°C are permitted
	Decision of 288: Deferred for following: 1. Clarification regarding diluent for reconstitution of product 2. Clarification of applied dosage form whether lyophilized powder or lyophilized cake in comparison to Innovator product approved by Reference Regulatory Authorities. Remarks of evaluator [VII]: The dosage form is lyophilized powder for injection the diluent is water for injection to provide concentration of 3.33mg/ml. **Decision: Deferred for confirmation of status of DSL status as expired on 7th April 2020.**	
1280.	Name and address of Applicant	M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt
	Detail of Drug Sale License	Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan Validity: 7-April- 2020 Status: License to sell drug as distributor
	Name and address of manufacturer	M/s Philinter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam

<table>
<tr><td></td><td>Name and address of marketing authorization holder</td><td>M/s Phil inter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam</td></tr>
<tr><td></td><td>Name of exporting country</td><td>Vietnam</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5-A</td></tr>
<tr><td></td><td>Diary No. & Date of R& I</td><td>Dy. No.26366 Dated 28-12-2017</td></tr>
<tr><td></td><td>Fee including differential fee</td><td>Rs. 50,000/- Dated 28-12-2017</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Colvagl Soft gel Capsule (Vaginal inserts)</td></tr>
<tr><td></td><td>Composition</td><td>Each Capsule Contains:
Nystatin…200,000IU
Nifuratel…500mg</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Manufacturere</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Gynecological anti-infective and antiseptic</td></tr>
<tr><td></td><td>Shelf life</td><td>36 months</td></tr>
<tr><td></td><td>Demanded Price</td><td>Decontrolled</td></tr>
<tr><td></td><td>Pack size</td><td>100 g, 500 g, 1000g</td></tr>
<tr><td></td><td>International availability</td><td>Inimur Complex by Polichem Sr (AIFA, Itley)</td></tr>
<tr><td></td><td>Me-too status</td><td>NA</td></tr>
<tr><td></td><td>Detail of certificates attached</td><td><u>Certificate of pharmaceutical products Copy embassy attested (COPP):</u>
Certificate No: 110241Gp-QLO
Certifying Authority: Ministry of health vietnam
Date of Review: June 12-2019
<u>GMP certificate (Copy, Notary Attested, Embassy attested)</u>
<u>Certificate No</u>:24g/GCNQLD
<u>Certifying Authority</u>: Ministry of health Vietnam
Issue Date: 14-6-2016</td></tr>
<tr><td></td><td>Remarks of the Evaluator [VII].</td><td>
<table>
<tr><th>S. NO</th><th>Remarks</th><th>Response</th></tr>
<tr><td>1.</td><td>A DSL copy in the name of M/s B.M Biotech, 73-B, Guldasht town, Zarrar shaheed road, Lahore cant, Pakistan Validity: 7-April-2020 was provided which is not valid now and the name is written as BM biotech instead of Bristol Myer Biotec</td><td>The application receipt for valid licence is attached</td></tr>
<tr><td>2.</td><td>Evidence of approval of applied formulation in RRA is not valid as reference of Cambodia, Korea and Vietnam was provided by the firm.</td><td>Inimur Complex By Polichem Srl "500 Mg + 200000 Iu Soft Vaginal Capsules (Itley approved)</td></tr>
<tr><td>3.</td><td>Original legalized and Valid COPP needed.</td><td>Provided</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech.</td></tr>
<tr><td>1281.</td><td>Name and address of Applicant</td><td>M/s Premier Agencies. 1A/15, Sector 15, Korangi Industrial Area, Karachi, Pakistan</td></tr>
</table>

	Detail of Drug Sale License	Address: M/s Premier Agencies. (godown) Plot No. D-3, D-4 and D5 sector 6-F, Mehran town Karachi, Pakistan Validity: 14-May-2020 Status: Drug License by Way of wholesale
	Name and address of manufacturer	M/s GE Healthcare Ireland Limited. I.D.A. Business Park, Carrigtohill, Co. Cork, Ireland
	Name and address of product license holder	GE healthcare AS PO box 4220 Nydalen, NO-0401 Oslo Norway
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.3306 Dated 25-1-2018
	Fee including differential fee	Rs. 100,000/- (Challan # 0702603) Dated 16-Jan-2018
	Brand Name +Dosage Form + Strength	Omnipaque 350mg/ml Injection
	Composition	Each 1 ml of omnipaque solution for injection Contains 775 mg and 200 ml of solution contains Iohexol …151g (Calculated on anhydrous base)
	Finished Product Specification	Manufacturer
	Pharmacological Group	X-ray contrast media (Iodinated)
	Shelf life	36 months
	Demanded Price	As per PRC
	Pack size	As per PRC, Polypropylene bottle (200 ml)
	International availability	Omnipaque 350 (USFDA)
	Me-too status	Iobrix of Hoffman Health Pakistan Ltd (Reg# 032124)
	Detail of certificates attached	Certificate of pharmaceutical products (Original, embassy attested (COPP): Certifying Authority: HPRA Health product regulatory authority Kevin O Malley house, Earlsfort center, Earlsfort terrace Dublin 2, Ireland Date of issue: 29-April 2019 Letter of authorization (Original, Notary Attested, Embassy attested) Issue Date: 16 May 2019 Certificate of GMP (Copy embassy attested: Certificate No: 13650 Certifying Authority: Health products regulatory authority HPRA Dated: 19 August 2016
	Remarks of the Evaluator [VII].	In USP Iohexol injection is present.

The address of importer in Pakistan is not as per provided DSL, in form 5-A and letter of authorization, submit form 5-A and letter of authorization with correct address which should be in-lined with DSL.	Authority letter and Form 5-A with address of importer which is in line with DSL is provided
As per explanatory note provided with COPP, The fill volume of 200 ml bottle is either 150, 175 ml or 200 ml Clarification is needed regarding your filled volume in 200 ml bottle.	The filled volume is 200 ml for injection

		<table><tr><td></td><td></td></tr><tr><td>Clarification is needed regarding the batch release site whether the stability according to zone IVA is done in Ireland (manufacturing site as per COPP) or in china</td><td>Firm clarify that the stability according to zone IV-A is done by GE healthcare Ireland Limited.</td></tr></table>
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
1282.	Name and address of Applicant	M/s Premier Agencies. 1A/15, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Detail of Drug Sale License	Address: M/s Premier Agencies. (godown) Plot No. D-3, D-4 and D5 sector 6-F, Mehran town Karachi, Pakistan Validity: 14-May-2020 Status: Drug License by Way of wholesale
	Name and address of manufacturer	M/s GE Healthcare Ireland Limited. I.D.A. Business Park, Carrigtohill, Co. Cork, Ireland
	Name and address of marketing authorization holder	GE healthcare AS PO box 4220 Nydalen, NO-0401 Oslo Norway
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.3307 Dated 27-1-2018
	Fee including differential fee	Rs. 100,000/- (Challan # 0702602) Dated 16-Jan-2018
	Brand Name +Dosage Form + Strength	Visipaque 320mg/ml Injection
	Composition	Each 1 ml of Visipaque solution for injection contains 652 mg and 50 ml of solution contains 32.6g, 75 ml contains 48.9g and 100 ml contain 65.2 g of Iodixanol (Calculated on anhydrous base)
	Finished Product Specification	Manufacturer
	Pharmacological Group	X-ray contrast media
	Shelf life	36 months
	Demanded Price	As per SRO
	Pack size	As per PRC, Polypropylene bottle (100 ml)
	International availability	Visipaque 320 (USFDA)
	Me-too status	Visipaque of Meximp Technologies (043052)
	Detail of certificates attached	Certificate of pharmaceutical products (Original, embassy attested (COPP): Certifying Authority: HPRA Health product regulatory authority Kevin O Malley house, Earlsfort center, Earlsfort terrace Dublin 2, Ireland Date of issue: 29-April 2019 Letter of authorization (Original, Notary Attested, Embassy attested) Issue Date: 16 May 2019 Certificate of GMP (Copy embassy attested: Certificate No: 13650 Certifying Authority: Health products regulatory authority HPRA Dated: 19 August 2016

	Remarks of the Evaluator [VII].	<table><tr><td>The address of importer in Pakistan is not as per provided DSL, in form 5-A and letter of authorization, submit form 5-A and letter of authorization with correct address which should be in-lined with DSL.</td><td>Authority letter and Form 5-A with address of importer which is in line with DSL is provided</td></tr><tr><td>As per explanatory note provided with COPP, The fill volume of 100 ml bottle is either 75 ml or 100 ml Clarification is needed regarding your filled volume in 100 ml bottle.</td><td>The filled volume is 100 ml for injection</td></tr><tr><td>Clarification is needed regarding the batch release site whether the stability according to zone IVA is done in Ireland (manufacturing site as per COPP) or in china</td><td>Firm clarify that the stability according to zone IV-A is done by GE healthcare Ireland Limited.</td></tr></table>
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
1283.	Name and address of Applicant	M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt
	Detail of Drug Sale License	Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan Validity: 7-April- 2020 Status: License to sell drug as distributor
	Name and address of manufacturer	M/s Philinter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam
	Name and address of marketing authorization holder	M/s Phil inter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.26364 Dated 28-12-2017
	Fee including differential fee	Rs. 50,000/- Dated 28-12-2017
	Brand Name +Dosage Form + Strength	Philvolte Cream
	Composition	Each 10g tube contains: Clotrimazole…100mg Betamethasone dipropionate…6.4mg Gentamicin sulfate…10mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Topical anti-infective and corticosteroid
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	10g

<table>
<tr><td></td><td>International availability</td><td>NA (Triderm ® crème: 1 g cream contains: Betamethasonum 0.5 mg, Clotrimazolum 10 mg, Gentamicinum 1 mg)</td></tr>
<tr><td></td><td>Me-too status</td><td>NA</td></tr>
<tr><td></td><td>Detail of certificates attached</td><td><u>Certificate of pharmaceutical products Copy embassy attested (COPP):</u>
Certificate No: 110241Gp-QLO
Certifying Authority: Ministry of health vietnam
Date of review: June 12-2019
<u>GMP status</u> confirmed on COPP</td></tr>
<tr><td></td><td>Remarks of the Evaluator [VII].</td><td>
<table>
<tr><th>S. NO</th><th>Remarks</th><th>Response</th></tr>
<tr><td>1.</td><td>A DSL copy in the name of M/s B.M Biotech, 73-B, Guldasht town, Zarrar shaheed road, Lahore cant, Pakistan Validity: 7-April-2020 was provided which is not valid now and the name is written as BM biotech instead of Bristol Myer Biotec</td><td>The application receipt for valid licence is attached</td></tr>
<tr><td>2.</td><td>Evidence of approval of applied formulation in RRA is not valid as reference of Cambodia, Korea and Vietnam was provided by the firm.</td><td>Firm provide the evidence of RRA in swiss medics as Triderm ® crème in which 1 g cream contains: Betamethasonum 0.5 mg, Clotrimazolum 10 mg, Gentamicinum 1 mg) but apllied product has 6.4 mg of betamethasone</td></tr>
<tr><td>3.</td><td>Original legalized and Valid COPP needed.</td><td>Original legalized COPP is provided</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech.</td></tr>
<tr><td>1284.</td><td>Name and address of Applicant</td><td>M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt</td></tr>
<tr><td></td><td>Detail of Drug Sale License</td><td>Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan
Validity: 7-April- 2020
Status: License to sell drug as distributor</td></tr>
<tr><td></td><td>Name and address of manufacturer</td><td>M/s Philinter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam</td></tr>
<tr><td></td><td>Name and address of marketing authorization holder</td><td>M/s Phil inter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam</td></tr>
<tr><td></td><td>Name of exporting country</td><td>Vietnam</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5-A</td></tr>
<tr><td></td><td>Diary No. & Date of R& I</td><td>Dy. No.26364 Dated 28-12-2017</td></tr>
</table>

<table>
<tr><td></td><td>Fee including differential fee</td><td>Rs. 50,000/- Dated 28-12-2017</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Gentrikin cream</td></tr>
<tr><td></td><td>Composition</td><td>Each 10gm Tube Contains:
Econazole Nitrate…100mg
Triamcinolone acetonide…10mg
Gentamicin Sulfate…10mg</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Manufacturer</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Topical anti-infective and corticosteroid</td></tr>
<tr><td></td><td>Shelf life</td><td>36 months</td></tr>
<tr><td></td><td>Demanded Price</td><td>Decontrolled</td></tr>
<tr><td></td><td>Pack size</td><td>10g</td></tr>
<tr><td></td><td>International availability</td><td>NA</td></tr>
<tr><td></td><td>Me-too status</td><td>NA</td></tr>
<tr><td></td><td>Detail of certificates attached</td><td><u>Certificate of pharmaceutical products Copy embassy attested (COPP):</u>
Certificate No: 1025/GP-QLD
Certifying Authority: Ministry of health vietnam
Date of validitity: June 12-2019
<u>GMP certificate (Copy, Notary Attested, Embassy attested)</u>
Certificate No:24g/GCNQLD
Certifying Authority: Ministry of health Vietnam
Issue Date: 14-6-2016</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>
<table>
<tr><th>S. NO</th><th>Remarks</th><th>Response</th></tr>
<tr><td>1.</td><td>A DSL copy in the name of M/s B.M Biotech, 73-B, Guldasht town, Zarrar shaheed road, Lahore cant, Pakistan Validity: 7-April-2020 was provided which is not valid now and the name is written as BM biotech instead of Bristol Myer Biotec</td><td>The application receipt for valid licence is attached</td></tr>
<tr><td>2.</td><td>Evidence of approval of applied formulation in RRA is not valid as reference of Cambodia, Korea and Vietnam was provided by the firm.</td><td>Firm provide the evidence in Mayanmar as it is not present in RRA</td></tr>
<tr><td>3.</td><td>Original legalized and Valid COPP needed.</td><td>Original legalized COPP is provided</td></tr>
<tr><td>4.</td><td>Orignal authority letter</td><td>Provided</td></tr>
<tr><td>5.</td><td>Stability protocols</td><td>Provided</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech.</td></tr>
<tr><td>1285.</td><td>Name and address of Applicant</td><td>M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt</td></tr>
<tr><td></td><td>Detail of Drug Sale License</td><td>Address: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan
Validity: 7-April- 2020</td></tr>
</table>

		Status: License to sell drug as distributor
	Name and address of manufacturer	M/s Philinter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong, Vietnam
	Name and address of marketing authorization holder	M/s Phil inter pharma Co; Ltd, No 25, street# 8, VSIP, Thuan An, Binh Duong 824060, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.26364 Dated 28-12-2017
	Fee including differential fee	Rs. 50,000/- (#0702406) Dated 28-12-2017
	Brand Name +Dosage Form + Strength	Vagicare soft gel capsule
	Composition	Each soft gel capsule Contains: Promestriene……. 10 mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Estrogens
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	10g
	International availability	Gynogyne 10 mg, vaginal soft capsule (ANSM France)
	Me-too status	NA
	Detail of certificates attached	Certificate of pharmaceutical products Copy embassy attested (COPP): Certificate No: 1021/GP-QLD Certifying Authority: Ministry of health Vietnam Date of review: 10 sep 2018 GMP certificate (Copy, Notary Attested, Embassy attested) Certificate No:24g/GCNQLD Certifying Authority: Ministry of health Vietnam Issue Date: 14-6-2016 GMP is confirmed from COPP
	Remarks of the Evaluator.	

Sr. No.	Remarks	Response
1.	A DSL copy in the name of M/s B.M Biotech, 73-B, Guldasht town, Zarrar shaheed road, Lahore cantt, Pakistan. Validity: 7-April-2020 was provided which is not valid now and the name is written as BM biotech instead of Bristol Myer Biotec	The application receipt for valid licence is attached.
2.	Evidence of approval of applied formulation in RRA is not valid as reference of Cambodia, Korea and Vietnam was provided by the firm.	Reference of Gynogyne 10 mg, vaginal soft capsule (ANSM France) was provided.
3.	Original legalized and Valid COPP needed.	Original legalized COPP is provided
4.	Original authority letter	Provided
5.	Stability protocols	Provided

	Decision: Deferred for following: **Submission of stability study data as per Zone IVA.** **Clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech.**	

Case No. 6 Miscellaneous cases

1286.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited. 1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Shahrah-e-Faisal, Karachi
	Brand Name +Dosage Form + Strength	Xadine 30mg/5ml Suspension
	Composition	Each 5ml Contains: Fexofenadine HCL…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2687 dated 21-01-2019 Rs.20,000/- Dated 18-01-2019 (#0799839)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x60 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	TELFAST ORAL LIQUID fexofenadine hydrochloride 6 mg/mL oral suspension bottle. TGA approved
	Me-too status	Telfast Suspension by M/s Sanofi Aventis (Reg. # 058699)
	GMP status	Last GMP inspection report dated 13-2-2018: Follow-up, as per the data provided by QALT Division.
	Remarks of Evaluator [VII]	
	Decision 295: Approved with innovator's specification Remarks: In the meeting of 295 the address of manufacturer of the above case was mentioned as M/s The Searle Company Limited. 1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Shahrah-e-Faisal, Karachi (Head quarter address) but the correct Factory address as per Form 5 was M/s The Searle Company Limited.32 km multan road, Lahore. **Decision: Approved with change in address from M/s The Searle Company Limited. 1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Shahrah-e-Faisal, Karachi (Head quarter address) to M/s The Searle Company Limited.32 km Multan road, Lahore.**	

Evaluator-PEC-VIII
Item No. I: Agenda of Evaluator PEC-VIII
Case no. 01 Registration applications for local manufacturing of (Human) drugs
b. Deferred cases

1286.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Pizo 0.5mg Tablet
	Composition	"Each Sugar-Coated Tablet Contains: Pizotifen (as maleate) …0.5mg"
	Diary No. Date of R& I & fee	Dy. No. 37116/4 dated 09-11-2018 Rs.20,000/-
	Pharmacological Group	Antimigraine)

	Type of Form	Form-5
	Finished product Specifications	JP Specifications (not found)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Mosegor 0.5mg sugar coated tablet of M/s Novartis
	GMP status	Dated: 10-10-2018 & 17-10-2018 Recommendations: Firm has been adhering to GMP guidelines and showing good compliance with quality policy completely implemented. Guidelines, SOP‟s and written instructions for each and every step in manufacturing testing, and storage ensuring quality products are intact and implemented. Keeping in view the above, the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator VIII	Evidence of approval of applied formulation as sugar coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting & also submit master formulation &manufacturing in line with reference product.
	Decision 295: Deferred for evidence of approval of applied formulation as sugar coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting & also submit master formulation & manufacturing in line with reference product. Remarks VIII: Firm provided the reference of Sandomigran (Pizotifen Malate) Tablet sugar coated approved in TGA Australia. **Decision: Approved**	
1287.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Welfax SR 50mg Tablet
	Composition	"Each Extended Release Film Coated Tablet Contains: Desvenlafaxine (as Succinate)…50mg"
	Diary No. Date of R& I & fee	Dy. No. 21237 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Qrist 50mg Tablet of Nabiqasim Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of the Evaluator VIII	Applied formulation is extended release tablet; name the extended release polymers as it is not present in master formulation. Firm has submitted a master formulation having extended release polymer Incorporated into core & coat of tablet.
	Decision 295: Deferred for clarification/justification regarding addition of extended release polymer in core & coat of tablet or else submission of master formulation & manufacturing method in-line with innovator. Remarks VIII: Copy of revised master formulation and method of manufacturing provided for extended release film coated tablet was provided with fee of 20,000/- (#2028798) dated 7 July 2020 **Decision: Approved with innovator's specification.**	

1288.	Name and address of manufacturer / Applicant	"M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad"
	Brand Name +Dosage Form + Strength	Terbipearl 1% Cream
	Composition	"Each Gram Contains: Terbinafine as HCL…1% w/w"
	Diary No. Date of R& I & fee	Dy. No. 38920 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	Anti-Fungal
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Exinofin Cream of Brookes Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 23-07-2018 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator (VIII)	Reference product is approved as Terbinafine hydrochloride 1.0% w/w cream which is different from applied formulation i.e. Terbinafine as HCL 1% w/w"& also submit label claim of applied formulation in line with innovator product. Mention primary packaging material for applied formulation.
	Decision 295: Deferred for the following: Reference product is approved as Terbinafine hydrochloride 1.0% w/w cream which is different from applied formulation i.e. Terbinafine as HCL 1% w/w"& also submit label claim of applied formulation in line with innovator product. Mention primary packaging material for applied formulation. Remarks VIII: GMP dated 23-7-2018with satisfactory GMP compliance. Firm responded that each gram of terbipearl 1% cream contain 10 mg terbinafine HCL which is in line with Lamisil 1% cream an DA approved product of Novartis USA. Copy of relevant pages of Form 5 were provided too. Primary packaging is collapsible aluminum tubes. **Decision: Approved with innovator's specification.**	
1289.	Name and address of manufacturer / Applicant	"M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad"
	Brand Name +Dosage Form + Strength	Linzopearl 100mg/5ml Oral Suspension
	Composition	"Each 5ml Contains: Linezolid…100mg"
	Diary No. Date of R& I & fee	Dy.No 38921 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	(60ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Linzol 100mg /5ml oral dry suspension of M/s Regal Pharmaceuticals
	GMP status	GMP inspection conducted on 23-07-2018 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator (VIII)	Mention type of primary packaging material of applied formulation. Mention polymeric form of Linezolid
	Decision of 295: Deferred for the following: Mention type of primary packaging material of applied formulation.	

	Mention polymeric form of Linezolid. Remarks VIII: GMP dated 23-7-2018with satisfactory GMP compliance Amber color glass bottle of 120 ml **Decision: Approved with innovator's specification.**

Case No. 02 Registration applications for local manufacturing of (veterinary) drugs
b. Deferred Cases

1290.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Floron Oral Powder
	Composition	Each gram contains: Neomycin Sulphate …….....150 mg Florfenicol……100 mg Oxytetracycline hydrochloride…..…300 mg
	Diary No. Date of R& I & fee	Dy. No. 21143 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Aminoglycoside/Antibiotic
	Type of Form	Form-5
	Finished product Specifications	As per innovator
	Pack size & Demanded Price	0.5kg, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status (with strength and dosage form)	E.Col Oral Powder of Evergreen Pharma Registrtion No. 081733 (not verifiable)
	GMP status	Oral Liquid section (general)(veterinary)Letter Issuance Date: 26th September, 2019. On recommendation of panel of experts CLB in its 271st meeting held on 12th September, 2019 has considered & approved following six additional section of M/s. Grand Pharma: 1. Bolus section (general)(veterinary) 2. Oral Powder section (general)(veterinary) 3. Oral Liquid section (general)(veterinary) 4. Oral Powder section (penicillin)(veterinary) 5. Dry Powder Injection section Vials (penicillin)(veterinary) 6. Liquid Injection section Vials (penicillin)(veterinary)
	Remarks of the Evaluator VIII	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision 295: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Remarks VIII: Me-too of E.Col Oral Powder of Evergreen Pharma Registrtion No. 081733 was provided by the firm.	
	Decision: Approved with innovator's specification.	
1291.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Enro-Hexin Oral Liquid Suspension
	Composition	"Each 100ml Contains: Enrofloxacin…10gm Bromhexine Hcl…1gm Colistin Sulphate…55 MIU"

	Diary No. Date of R& I & fee	Dy.No 21156 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic / Expectorant
	Type of Form	Form-5
	Finished product Specifications	As per innovator
	Pack size & Demanded Price	100ml, 500ml, 1liter; Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status (with strength and dosage form)	En-C-Raft Oral Liquid of NAWAL PHARMA (Reg# 078251) (not verifiable)
	GMP status	Oral Liquid section (general)(veterinary)Letter Issuance Date: 26th September, 2019. On recommendation of panel of experts CLB in its 271st meeting held on 12th September, 2019 has considered & approved following six additional section of M/s. Grand Pharma: 1. Bolus section (general)(veterinary) 2. Oral Powder section (general)(veterinary) 3. Oral Liquid section (general)(veterinary) 4. Oral Powder section (penicillin)(veterinary) 5. Dry Powder Injection Section Vials (penicillin)(veterinary) 6. Liquid Injection section Vials (penicillin)(veterinary)
	Remarks of the Evaluator VIII	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision 295: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Remarks VIII: Firm revised their master formulation and form 5 with formulation of "Each 100ml Contains: Enrofloxacin…10gm Bromhexine Hcl…0.5 mg Colistin Sulphate…55 MIU" Me too: En-C-Raft Oral Liquid of NAWAL PHARMA (Reg# 078251) (Firm claim to submit fee of 5000/- but no fee challan was attached) **Decision: Deferred for submission of requisite fee for revision of formulation as per the reference product**	
1292.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	G-Flor Plus Oral Liquid
	Composition	"Each 100ml Contains: Florfenicol…23gm Colistin Sulphate…50 MIU"
	Diary No. Date of R& I & fee	Dy.No 21148 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic / Expectorant
	Type of Form	Form-5
	Finished product Specifications	As per innovator
	Pack size & Demanded Price	500ml, 1liter, 2.5liter, 5liter; Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status (with strength and dosage form)	NA Maxiflor Plus Oral Liquid of BIOGEN Pharma (Reg# 075617). Each 1000ml Contains: - Florfenicol……23gm

		Colistin Sulphate...50 MIU
	GMP status	Oral Liquid section (general)(veterinary)Letter Issuance Date: 26th September, 2019. On recommendation of panel of experts CLB in its 271st meeting held on 12th September, 2019 has considered & approved following six additional section of M/s. Grand Pharma: 1. Bolus section (general)(veterinary) 2. Oral Powder section (general)(veterinary) 3. Oral Liquid section (general)(veterinary) 4. Oral Powder section (penicillin)(veterinary) 5. Dry Powder Injection Section Vials (penicillin)(veterinary) 6. Liquid Injection section Vials (penicillin)(veterinary)
	Remarks of the Evaluator VIII	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision 295: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Remarks VIII: The provided reference of Fenicol 23 oral liquid (# 0080731) of Baariq Pharma can't be verified. **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1293.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Doxy-Hy 50 Oral Powder
	Composition	Each kg contains: Doxycycline Hyclate (BP)……500 gm
	Diary No. Date of R& I & fee	Dy. No. 21140 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	0.5kg, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status (with strength and dosage form)	Doxyvetz Oral Powder of M/s Vetz Pharma Reg. No.088059 (not verifiable)
	GMP status	Date: 26th September, 2019. On recommendation of panel of experts CLB in its 271st meeting held on 12th September, 2019 has considered & approved following six additional section of M/s. Grand Pharma: 1. Bolus section (general)(veterinary) 2. Oral Powder section (general)(veterinary) 3. Oral Liquid section (general)(veterinary) 4. Oral Powder section (penicillin)(veterinary) 5. Dry Powder Injection section Vials (penicillin)(veterinary) 6. Liquid Injection section Vials (penicillin)(veterinary)
	Remarks of the Evaluator VIII	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision (M-294): Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Remarks of the Evaluator VIII Now the Applicant has Submitted Evidence of following Me Too: Seldox Powder of Selmore Pharmaceuticals	

<table>
<tr><td></td><td colspan="2">Each G Contains: -
Doxycycline Hyclate…..500mg.
*applied formulation is in kg but me too product is in grams.
<u>Decision 295:</u> Deferred for either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise revision of formulation in line with provided Me Too alongwith submission of requisite fee as the provided evidence is in gram while applied formulation contains same quanity of ingredient per kg.
<u>Remarks VIII:</u> The firm submitted that “the same formulation Se-Dox 50 (Each kg contains: Doxycycline Hyclate (BP)……..……500 gm) with same reference of Seldox Powder of Selmore Pharmaceuticals (Each g contains: Doxycycline Hyclate (BP)……..……500 mg) is approved in 291 meeting of DRB for vetec lab so kindly carry forward our case too”
Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.</td></tr>
<tr><td>1294.</td><td colspan="2">Deleted</td></tr>
<tr><td>1295.</td><td colspan="2">Deleted</td></tr>
<tr><td>1296.</td><td>Name and address of manufacturer / Applicant</td><td>"M/s Elegance Pharmaceuticals.
Chak Belli Pandori Road, Distt. Rawalpindi"</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Amantacin 10gm Powder</td></tr>
<tr><td></td><td>Composition</td><td>Each 100gm Contains:
Amantadine HCL…10gm</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy.No 34438 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Anti-viral</td></tr>
<tr><td></td><td>Type of Form</td><td>Form-5</td></tr>
<tr><td></td><td>Finished product Specifications</td><td>Manufacturer’s Specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>Decontrolled</td></tr>
<tr><td></td><td>Me-too status (with strength and dosage form)</td><td></td></tr>
<tr><td></td><td>Me-too status (with strength and dosage form)</td><td>Could not be confirmed</td></tr>
<tr><td></td><td>GMP status</td><td>---</td></tr>
<tr><td></td><td>Remarks of the Evaluator (VIII)</td><td>Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
Submit latest GMP inspection report.</td></tr>
<tr><td></td><td colspan="2">Decision of 295: Deferred for the following:
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.
Approval of section/manufacturing facility by the Central Licensing Board.
Latest GMP inspection report.
Remarks VIII:
<table>
<tr><td>Remarks</td><td>Firm response</td></tr>
<tr><td>Submit latest GMP inspection report.</td><td>GMP dated 5th Oct 2019 with GMP compliant</td></tr>
<tr><td>Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.</td><td>Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)</td></tr>
</table></td></tr>
</table>

		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Amantabak 10% powder by M/S Attabak pharma (# 075697)
	Decision: Approved with innovator's specification.		
1297.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"	
	Brand Name +Dosage Form + Strength	NFO Powder	
	Composition	Each 1000gm Contains: Florfenicol…100gm Oxytetracycline HCL…300gm Neomycin Sulphate…150gm	
	Diary No. Date of R& I & fee	Dy.No 34440 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018	
	Pharmacological Group	Antibiotic	
	Type of Form	Form-5	
	Finished product Specifications	Manufacturer's Specifications	
	Pack size & Demanded Price	decontrolled	
	Me-too status (with strength and dosage form)	Could not be confirmed	
	GMP status	----	
	Remarks of the Evaluator (VIII)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable. Submit latest GMP inspection report.	
	Decision of 295: Deferred for the following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. Submit latest GMP inspection report.		
		Remarks	Firm response
		Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
		Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Firm modified there composition from Each 1000gm Contains: Florfenicol…100gm Oxytetracycline HCL…300gm Neomycin Sulphate…150gm as Each gm Contains: Florfenicol…100 mg Oxytetracycline HCL…300 mg Neomycin Sulphate…150 mg Me too: Amantabak 10% powderZ-florcin wsp by M/S Zoic international (# 090680) With fee of 5000/- (#1953374) dated 13-8-2020

	Decision: Approved with innovator's specification.	
1298.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Interflor 250mg/ml Liquid
	Composition	Each ml Contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 34439 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	-----
	Remarks of the Evaluator (VIII)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.
	Decision of 295: Deferred for the following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	

Remarks	Firm response
Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	FLORFENICOL ORAL LIQUID by M/S Attaback Pharma (# 075707)

	Decision: Approved with innovator's specification.	
1299.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Doxyl-80 Powders
	Composition	Each gm Contains: Doxycycline Hyclate 918.23mg Eq. to Doxycycline Base…800mg
	Diary No. Date of R& I & fee	Dy. No. 34441 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed

	GMP status	----
	Remarks of the Evaluator (VIII)	

Decision of 295:
Deferred for the following:
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, as the provided Me Too is not verifiable.
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.

Remarks	Firm response
Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Doxyral 80% Water Soluble Powder For Oral ROUTE by M/S Orient (#'082504) Each Gram of Water-Soluble Powder Contains: - Doxycycline Hyclate…...923.32mg (Eq. To 800mg Doxycycline)

Decision: Approved with innovator's specification.

1300.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Encopol Liquid
	Composition	Each ml Contains: Enrofloxacin…20% Colistin Sulphate…3%
	Diary No. Date of R& I & fee	Dy.No 34443 dated 17-10-2018 Rs.20,000/- 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	----
	Remarks of the Evaluator (VIII)	Please clarify the following: Enrofloxacin… 20%/ml & Colistin Sulphate…3%"/ml. what does it mean? Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility

	Decision of 295: Deferred for the following: Please clarify the following: Enrofloxacin… 20%/ml & Colistin Sulphate…3%"/ml. what does it mean? Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility	

Remarks	Firm response
Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Firm modified there composition from Each ml Contains: Enrofloxacin…20% Colistin Sulphate…3% as Each 100 ml Contains: Enrofloxacin…20% Colistin Sulphate…3% Me too: ENROSIR-20 ORAL LIQUID by M/S ATTABAK PHARMA (# 090680) With fee of 5000/- (#1953375) dated 13-8-2020

Decision: Approved with innovator's specification.

1301.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Enro Ts Liquid
	Composition	Each ml contains: Enrofloxacin…75mg Sulphamethoxy Pyridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R & I & fee	Dy. No. 9229; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 500ml, 1L; Decontrolled
	Me-too status	CINA T.S ORAL SUSPENSION. Reg. NO. 31456 (enroflodicaine has been mentioned instead of enrofloxacin).
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	The firm mentioned Sulphamethoxy Pyridazine in the label claim and Sulphamethoxy Pyridazine as sodium in the master formula and manufacturing outlines. Upon justification the firm revised the master formula.

Decision of 295:

Deferred for the following:

Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, as the provided Me Too is not verifiable.

Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.

Remarks	Firm response
Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Cina T.S Oral Suspension By Leads (#031456) (Each ml Contains:- Trimethorpim 25mg. Sulphamethazine 50mg. Sulphamethoxyparadazine 75mg. Enroflodacine (Cenoxine) 75mg)

Decision: Approved with innovator's specification.

1302.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Doc Powder
	Composition	Each 100gm contains: Doxycycline HCL…20gm Colistin sulphate…40,000,000IU Carrier q.s.…100gm
	Diary No. Date of R & I & fee	Dy. No. 9222; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	DOXYCOL DS ORAL POWDER. Reg. no. 31482
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	The firm has mentioned the carrier in the label claim. Upon clarification the firm submitted they have applied as per label of me-too product available in the market.

Decision of 295:

Deferred for clarification of carrier in the applied formulation.

Remarks	Firm response
Submit latest GMP inspection report.	GMP dated 5th Oct 2019 with GMP compliant
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Letter from licensing division for oral liquid syrup (Veterinary) and for oral dry powder (Veterinary)

	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Firm modified there composition from Each 100gm contains: Doxycycline HCL…20gm Colistin sulphate…40,000,000IU Carrier q.s.…100gm as Each 100gm contains: Doxycycline HCL…20gm Colistin sulphate…40,000,000IU Me too: DOXYCOL DS ORAL POWDER. by M/S Bio Lab (#'031482) With fee of 5000/- (#1953376) dated 13-8-2020
	Decision: Approved with innovator's specification.	
1303.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	E Linco Powder
	Composition	Each 100-gm powder contain Lincomycin HCl…4.4%
	Diary No. Date of R & I & fee	Dy. No. 9215; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Lincosamide
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	LINCOS-P POWDER. Reg. No. 49667
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	The firm was asked to clarify Lincomycin HCl…4.4%. The firm submitted they have applied as per label of me-too product available in the market.
	Decision of 295: Deferred for correction in the label claim of applied formulation.	
	Remarks	Firm response
	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.	Firm modified their composition from Lincomycin HCl…4.4% as Each 100 gm powder contain Lincomycin HCl…4.4% Me too: Lincos-P powder. by M/S Inshal pharma (#'093601) With fee of 5000/- (#1953377) dated 13-8-2020
	Decision: Approved with innovator's specification.	
1304.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Elecox Powder
	Composition	Each 100gm contains: Amprolium HCL…30gm Sulphaquinoxalin sodium…20gm Vitamin K3…600mg
	Diary No. Date of R & I & fee	Dy. No. 9223; 28.02.2019 PKR. 20,000/-; 28.02.2019

	Pharmacological Group	Treatment of coccidiosis + vitamin K
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	DYECOX WATER SOLUBLE POWDER. Reg. No. 74064
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	The firm was asked to revise the strength of APIs in line with the me-too product along with submission of applicable fee. The firm submitted they have applied as per label of me-too product available in the market.
	Decision of 295: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

Remarks	Firm response
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	Firm modified their formulation from Each kg contains: - Sulphaquinoxaline (as sodium). 200gm. Amprolium hcl. 300 gm. Vitamin k3 6 g. to Each 100gm contains: - Sulphaquinoxaline (as sodium) b.p. 20gm. Amprolium hcl b.p. 30gm. Vitamin k3 b.p. 600mg. Me too: DYECOX ORAL POWDER. By Biogen Pharma by M/S Bio Lab (#'031482) With fee of 5000/- (#1953378) dated 13-8-2020

Decision: Approved with innovator's specification.

1305.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Norfim S Liquid
	Composition	Each 100ml contains: Norfloxacin…10gm Sulphamethoxypyridazine sodium…15gm Trimethoprim…30gm
	Diary No. Date of R & I & fee	Dy. No.9224; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 500ml, 1 L; Decontrolled
	Me-too status	NORTRIM-S ORAL LIQUID. Reg. No. 75779
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	Revise the strength of APIs in line with the me-too product along with submission of applicable fee.

	Decision of 295: Deferred for revision of formulation as per me-too reference. **Remarks** / **Firm response** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm / Firm modified their formulation from Each 100ml contains: Norfloxacin…10gm Sulphamethoxypyridazine sodium…15gm Trimethoprim…30gm to Each 100ml contains: Norfloxacin…10gm Sulphamethoxypyridazine sodium…15gm Trimethoprim…3 gm Me too: Norplus Liquid By Biogen Pharma by M/S Attaback Pharma (#'034534) With fee of 5000/- (#1953379) dated 13-8-2020 **Decision: Approved with innovator's specification.**

Item No. I: Agenda of Evaluator PEC- XIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

1306.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	E- Cit tablet 20mg
	Composition	Each film coated tablet contains: Escitalopram as oxalate……..…20mg
	Diary No. Date of R & I & fee	Dy. No. 10788 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Citanew 20mg tablet of M/s Hilton Pharma, Korangi Industrial Area, Karachi (Reg. # 037681)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1307.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Levecetam tablet 250mg
	Composition	Each film coated oral tablet contains: Levetiracetam…….250mg
	Diary No. Date of R & I & fee	Dy.No.9488 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Leveticam 250mg tablet of M/s WnsFeild Pharma, Hattar (Reg. # 084220)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1308.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Levecetam tablet 500mg
	Composition	Each film coated oral tablet contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Dy.No.9489 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leveticam 500mg tablet of M/s WnsFeild Pharma, Hattar (Reg. # 084221)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1309.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pride tablet 100mg
	Composition	Each tablet contains: Amisulpride……...100mg
	Diary No. Date of R & I & fee	Dy.No.10301 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Solium- 100 tablet of M/s Genome Pharmaceuticals (Pvt.) Ltd, Hattar. (Reg. # 074533)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1310.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pride tablet 400mg
	Composition	Each film- coated tablet contains: Amisulpride……..400mg
	Diary No. Date of R & I & fee	Dy.No.10289 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as uncoated tablet

	Me-too status	Amirid of M/s Shrooq Pharma, Lahore (Reg. # 063103)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is approved as uncoated tablet in MHRA.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
1311.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Modnil tablet 100mg
	Composition	Each tablet contains: Modafinil…...100mg
	Diary No. Date of R & I & fee	Dy.No 10304 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Psycho- stimulant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	V- Zac Tablet 100mg of M/s Wilshire Laboratories, Lahore (Reg. # 055346)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1312.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Modnil tablet 200mg
	Composition	Each tablet contains: Modafinil…..200mg
	Diary No. Date of R & I & fee	Dy.No.10305 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Psycho- stimulant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	V- Zac Tablet 200mg of M/s Wilshire Laboratories, Lahore (Reg. # 055347)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1313.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Topigen tablet 25mg
	Composition	Each film coated tablet contains: Topiramate……....25mg
	Diary No. Date of R & I & fee	Dy.No.9864 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	30's, 60's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Topirat tablets 25mg of M/s Gray's Pharmaceuticals, Islamabad (Reg. # 040867)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1314.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Dil tablet 6.25mg
	Composition	Each film coated tablet contains: Carvedilol……6.25mg
	Diary No. Date of R & I & fee	Dy.No.10284 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Carveda tablet of M/s Ferozesons Labs, Nowshera (Reg. # 032569)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1315.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Dil tablet 12.5mg
	Composition	Each film coated tablet contains: Carvedilol……12.5mg
	Diary No. Date of R & I & fee	Dy.No.10285 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Carveda tablet of M/s Ferozesons Labs, Nowshera (Reg. # 056263)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1316.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Amlustar tablet 5/80mg
	Composition	Each film- coated tablet contains: Amlodipine besylate eq. to Amlodipine……..5mg Valsartan……80mg
	Diary No. Date of R & I & fee	Dy.No.9496 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019

	Pharmacological Group	Angiotensin- II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's, 2x 14's &As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge 5/ 80mg film- coated tablets of M/s Novartis Pharma (Pakistan) Limited, Karachi (Reg. # 047569)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1317.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Amlustar tablet 5/ 160mg
	Composition	Each film- coated tablet contains: Amlodipine besylate eq. to Amlodipine……..5mg Valsartan……..…160mg
	Diary No. Date of R & I & fee	Dy.No.9494 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's, 2x 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge 5/ 160mg film- coated tablets of M/s Novartis Pharma (Pakistan) Limited, Karachi (Reg. # 047570)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1318.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Amlustar tablet 10/ 320mg
	Composition	Each film- coated tablet contains: Amlodipine besylate eq. to Amlodipine……..……..10mg Valsartan……..…320mg
	Diary No. Date of R & I & fee	Dy.No.9493 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's, 2x 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge 10/ 320mg film- coated tablets of M/s Novartis Pharma (Pakistan) Limited, Karachi (Reg. # 069546)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.

		• The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1319.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Zolidin tablet 400mg
	Composition	Each film- coated tablet contains: Linezolid……400mg
	Diary No. Date of R & I & fee	Dy.No.9860 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 12's, 14's &As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Linezert tablet of M/s Albert Pharmaceuticals, Lahore (Reg. # 087558)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1320.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Zolidin tablet 600mg
	Composition	Each film- coated tablet contains: Linezolid……600mg
	Diary No. Date of R & I & fee	Dy.No 9861 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 12's, 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Linez 600mg Tablet of M/s Nexus Pharma (Pvt.)Ltd Korangi Industrial Area, Karachi (Reg. # 061309)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1321.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Zolidin Suspension 100mg/5ml
	Composition	Each 5ml contains: Linezolid……100mg
	Diary No. Date of R & I & fee	Dy.No.9859 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved

	Me-too status	Linez Dry 100mg/5ml Powder Suspension of M/s Nexus Pharma Karachi (Reg. # 081594)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General oral dry powder for suspension section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1322.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	T- Sart Tablet 20mg
	Composition	Each tablet contains: Telmisartan….20mg
	Diary No. Date of R & I & fee	Dy.No.10296 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Angiotensin- II Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30' &As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telmas tablets of M/s Global Pharmaceuticals, Islamabad(Reg. # 048333)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1323.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	T- Sart Tablet 80mg
	Composition	Each tablet contains: Telmisartan….80mg
	Diary No. Date of R & I & fee	Dy.No.10297 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Angiotensin- II Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30' & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telmas tablets of M/s Global Pharmaceuticals, Islamabad (Reg. # 048331)
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1324.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	T- Sart Tablet Plus 40mg/ 12.5mg
	Composition	Each tablet contains: Telmisartan……40mg Hydrochlorothiazide……...…12.5mg
	Diary No. Date of R & I & fee	Dy.No.9491 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II Antagonist/ Diuretics
	Type of Form	Form- 5
	Finished product Specification	USP

	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as bi- layered tablet
	Me-too status	Co Telmas 40mg Tablets of M/s Global Pharmaceuticals, Islamabad. 056285
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied drug is USFDA approved as bi- layered tablet.
	Decision: Deferred for the following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bilayered tablet, while the applied drug is mono layered tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.**	
1325.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	T- Sart Tablet Plus 80mg/ 12.5mg
	Composition	Each tablet contains: Telmisartan……80mg Hydrochlorothiazide……...…12.5mg
	Diary No. Date of R & I & fee	Dy.No.9492 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II Antagonist/ Diuretics
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as bi- layered tablet
	Me-too status	Co Telmas 80mg Tablets of M/s Global Pharmaceuticals, Islamabad. 056286
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied drug is USFDA approved as bi- layered tablet.
	Decision: Deferred for the following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bilayered tablet, while the applied drug is mono layered tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.**	
1326.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Lefmide Tablet 20mg
	Composition	Each film coated tablet contains: Leflunomide……...20mg
	Diary No. Date of R & I & fee	Dy.No.10302 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lefluno Tablet of M/s Caraway Pharmaceuticals, Islamabad. 050063

	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1327.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Losap Tablet 25mg
	Composition	Each film coated tablet contains: Losartan Potassium……....25mg
	Diary No. Date of R & I & fee	Dy.No.9473 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Sartan Tablets of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi 024250
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1328.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Losap Tablet 50mg
	Composition	Each film coated tablet contains: Losartan Potassium……....50mg
	Diary No. Date of R & I & fee	Dy.No.9474 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Angiotensin- II Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Losart 50mg Tablets of M/s Pearl Pharmaceuticals Islamabad 035650
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1329.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Coxib Tablet 60mg
	Composition	Each film coated tablet contains: Etoricoxib ……..60mg
	Diary No. Date of R & I & fee	Dy.No.9490 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoricox 60mg Tablet of Kaizen Pharma Karachi 076226

	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1330.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Tramol Plus Tablets 325mg/37.5mg
	Composition	Each film coated tablet contains: Paracetamol……..325mg Tramadol HCl…….37.5mg
	Diary No. Date of R & I & fee	Dy.No.9485 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ultragesic Tablet of Opal lab Karachi 076256
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1331.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Sitamet DS Tablet 50mg/1000mg
	Composition	Each film coated tablet contains: Sitagliptin as Phosphate Monohydrate……..50mg Metformin HCl……..1000mg
	Diary No. Date of R & I & fee	Dy.No.9484 dated 04-03-2019 Rs.20,000/- Dated 28-03-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 14's, 28's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Sitaglu Met 50/ 1000 Tablet of Hilton Pharma (Pvt.) Limited Karachi 055162
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1332.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pin 0.25mg Tablet
	Composition	Each film- coated tablet contains: Ropinirole as HCl…....0.25mg
	Diary No. Date of R & I & fee	Dy.No.10290 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- Parkinson drug
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 21's, 28's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ropinol 0.25mg Tablet of Amarant, Karachi 070779

	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1333.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pine 200mg Tablet
	Composition	Each film- coated tablet contains: Quetiapine as fumarate…..200mg
	Diary No. Date of R & I & fee	Dy.No.10294 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Qusel Tablet 200mg of M/s Hilton Pharma (Pvt.) Ltd, Karachi 037690
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1334.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pine 300mg Tablet
	Composition	Each film- coated tablet contains: Quetiapine as fumarate…..300mg
	Diary No. Date of R & I & fee	Dy.No.10295 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Qusel Tablet 300mg of M/s Hilton Pharma (Pvt.) Ltd, Karachi 037691
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1335.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Terbin Tablet 125mg
	Composition	Each Tablet Contains: Terbinafine as HCl……..125mg
	Diary No. Date of R & I & fee	Dy.No.9486 dated 01-03-2019 Rs.20,000/- Dated 28-03-2019
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lamisil Sandoz 125mg Tab of M/s Sandoz Karachi 013208

	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1336.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Terbin Tablet 250mg
	Composition	Each Tablet Contains: Terbinafine as HCl……..250mg
	Diary No. Date of R & I & fee	Dy.No.9487 dated 01-03-2019 Rs.20,000/- Dated 28-03-2019
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lamisil Sandoz 125mg Tab of M/s Sandoz Karachi 013209
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1337.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Lorx 4mg Tablet
	Composition	Each film- coated tablet contains: Lornoxicam……4mg
	Diary No. Date of R & I & fee	Dy.No.9476 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Lornox 4mg Tablet of M/s Ray Pharma (Pvt.) Ltd., Karachi 066713
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1338.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Lorx 8mg Tablet
	Composition	Each film-coated tablet contains: Lornoxicam……..8mg
	Diary No. Date of R & I & fee	Dy.No.9477 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30', 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved

	Me-too status	Lornox 8mg Tablet of M/s Ray Pharma (Pvt.) Ltd., Karachi 061083
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1339.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Sert Tablet 50mg
	Composition	Each film- coated tablet contains: Sertraline as HCl……..…50mg
	Diary No. Date of R & I & fee	Dy.No.9480 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- depressant/ SSRI
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zoloft Tablets 50mg of M/s Pfizer Laboratories Ltd, Karachi 020855
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1340.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Sert Tablet 100mg
	Composition	Each film- coated tablet contains: Sertraline as HCl……...…100mg
	Diary No. Date of R & I & fee	Dy.No.9481 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- depressant/ SSRI
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zoloft Tablets 50mg of M/s Pfizer Laboratories Ltd, Karachi 020856
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1341.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Top Tablet 200mg
	Composition	Each film- coated tablet contains: Topiramate……200mg
	Diary No. Date of R & I & fee	Dy.No.10298 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 60's & As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Topirax Tablets 200mg of M/s Feroza International Pharmaceuticals (Pvt.) Ltd,Lahore041657
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1342.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Febuxogood Tablet 40mg
	Composition	Each film- coated tablet contains: Febuxostat……....40mg
	Diary No. Date of R & I & fee	Dy.No.9498 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- gout
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Febux Tablet 40mg of M/s CCL Pharma Lahore 068106
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1343.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Febuxogood 80mg Tablet
	Composition	Each tablet contains: Febuxostat…..80mg
	Diary No. Date of R & I & fee	Dy.No.9499 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- gout
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France approved
	Me-too status	Febux Tablet 80mg of M/s CCL Pharma Lahore 068107
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
1344.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	BAC Tablet 10mg
	Composition	Each film- coated tablet contains: Baclofen…….....10mg
	Diary No. Date of R & I & fee	Dy.No.10303 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Muscle relaxant
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Lioresal 10mg Tablets of Novartis Pharma (Pakistan) Ltd, Karachi 027275
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1345.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Zapol Tablet 5mg
	Composition	Each film- coated tablet contains: Olanzapine as Citrate……5mg
	Diary No. Date of R & I & fee	Dy.No.9482 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olanzapine-Sandoz 5mg Tablets of M/s Novartis Pharma, Karachi 048411
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1346.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Zapol Tablet 10mg
	Composition	Each film- coated tablet contains: Olanzapine as Citrate……10mg
	Diary No. Date of R & I & fee	Dy.No.10299 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olanzapine- Sandoz 10mg Tablets of M/s Novartis Pharma, Karachi 048412
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1347.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Dula Capsule 30mg
	Composition	Each capsule contains: Duloxetine as HCl (enteric coated pellets) ……..30mg
	Diary No. Date of R & I & fee	Dy.No.9862 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulox 30mg Capsule of M/s Kaizen Pharma Karachi 076232
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • Source of pellets is M/s Vision Pharmaceuticals. • But stability data of pellets, CoA of manufacturer and GMP certificate of manufacturer of pellets is not submitted by the firm. • The official monograph for this applied formulation is available in USP.
	Decision: Deferred for stability studies data of pellets, CoA of manufacturer, GMP certificate of supplier and differential fee in case of import of pellets.	
1348.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Dula Capsule 60mg
	Composition	Each capsule contains: Duloxetine as HCl (enteric coated pellets)……..60mg
	Diary No. Date of R & I & fee	Dy.No.9863 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulox 60mg Capsule of M/s Kaizen Pharma Karachi 076231
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • Source of pellets is M/s Vision Pharmaceuticals. • But stability data of pellets, CoA of manufacturer and GMP certificate of manufacturer of pellets is not submitted by the firm. • The official monograph for this applied formulation is available in USP.
	Decision: Deferred for stability studies data of pellets, CoA of manufacturer, GMP certificate of supplier and differential fee in case of import of pellets.	
1349.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Omenate Capsule 20/1100mg
	Composition	Each capsule contains: Omeprazole……20mg Sodium bicarbonate……1100mg
	Diary No. Date of R & I & fee	Dy.No.9478 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Not submitted
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Omeprafast of M/s Bio-Labs (Pvt.) Ltd. 065376

	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • Applied pharmacological group is not mentioned. • The applied formulation is non- pharmacopoeial.
	Decision: Deferred for submission of applied pharmacological group.	
1350.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Omenate Capsule 40/ 1100mg
	Composition	Each capsule contains: Omeprazole……40mg Sodium bicarbonate……1100mg
	Diary No. Date of R & I & fee	Dy.No.9479 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	PPI/ Antacid
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Omeprafast of M/s Bio-Labs (Pvt.) Ltd. 065377
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • Applied pharmacological group is not mentioned. • The applied formulation is non- pharmacopoeial.
	Decision: Deferred for submission of applied pharmacological group.	
1351.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Gaybal Capsule 75mg
	Composition	Each Capsule Contains: Pregabalin……75mg
	Diary No. Date of R & I & fee	Dy.No.9866 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 7's &As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Pregalax Capsule of M/s Magns Pharmaceuticals, Faisalabad. 084136
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1352.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Gaybal Capsule 100mg
	Composition	Each Capsule Contains: Pregabalin……..100mg
	Diary No. Date of R & I & fee	Dy.No.9867 dated 04-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 7's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Pregalax Capsule of M/s Magns Pharmaceuticals, Faisalabad. 084137
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1353.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pineflux Capsule 3mg/25mg
	Composition	Each Capsule Contains: Olanzapine……..……..…3mg Fluoxetine HCl……..25mg
	Diary No. Date of R & I & fee	Dy.No.9503 dated 01-03-2019 Rs.20,000/- Dated 28-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 30's &As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Co- Depricap 3/ 25 Capsule of M/s Nabi Qasim, Karachi 076136
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1354.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pineflux Capsule 6mg/ 25mg
	Composition	Each Capsule Contains: Olanzapine……..……..…6mg Fluoxetine HCl……..25mg
	Diary No. Date of R & I & fee	Dy.No.9765 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Olanzakson Capsule of M/s Akson Pharmaceuticals Pvt Ltd, Islamabad 081659
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1355.	Name and address of manufacturer/ Applicant	M/s Goodman Laboratories, Plot No. 5, Street No. S- 05, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Pineflux Capsule 12mg/ 25mg
	Composition	Each Capsule Contains: Olanzapine……..……...12mg

		Fluoxetine HCl……..25mg
	Diary No. Date of R & I & fee	Dy.No.9497 dated 01-03-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Olanzakson DS Capsule of M/s Akson Pharmaceuticals Pvt Ltd, Islamabad 081658
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 08-08-2018.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
1356.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zestine 10mg Tablet
	Composition	Each tablet contains: Ebastine……..10mg
	Diary No. Date of R & I & fee	Dy.No.3480 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	USP/ BP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM; France as film- coated
	Me-too status	Ebastine 10mg Tabletsof M/s Alina Combine Karachi 045251
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	• Firm has General tablet section as mentioned in the submitted GMP certificate. • Approved in ANSM; France as film- coated while initially the firm applied uncoated tablet. • Now, the firm has revised the applied formulation according to the reference but has not submitted the requisite fees for revision of formulation. • USP or BP is applied while the official monograph for the applied formulation is in JP.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1357.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zetapram Tablet 5mg
	Composition	Each tablet contains: Escitalopram as Oxalate…….5mg
	Diary No. Date of R & I & fee	Dy.No.3483 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	SSRI
	Type of Form	Form- 5
	Finished product Specification	USP/ BP
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA as film- coated tablet
	Me-too status	Escital Tablet of M/s Helix Pharma 061634
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.

	Remarks of the Evaluator[XIII]	• Firm has General tablet section as mentioned in the submitted GMP certificate. • Approved in MHRA as film- coated while initially the firm applied uncoated tablet. • Now, the firm has revised the applied formulation according to the reference but has not submitted the requisite fees for revision of formulation. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1358.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zeprox 550mg Tablet
	Composition	Each tablet contains: Naproxen Sodium……...550mg
	Diary No. Date of R & I & fee	Dy.No.3482 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20' & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Crysanal 550mg film coated tablet by M/s Atnahs Pharma Australia Pty Ltd, TGA Australia Approved.
	Me-too status	Xaprox tablets 550mg of M/s Pfizer Pakistan (Reg.# 067374)
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	• Firm has General tablet section as mentioned in the submitted GMP certificate. • Approved in MHRA as film- coated while initially the firm applied uncoated tablet. • Now, the firm has revised the applied formulation according to the reference but has not submitted the requisite fees for revision of formulation. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1359.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zetadine Tablet 10mg
	Composition	Each film- coated tablet contains: Loratadine……10mg
	Diary No. Date of R & I & fee	Dy.No.3481 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA and Netherland as uncoated
	Me-too status	Senergy OD 10mg tablet of M/s Highnoon (Reg.# 017672)
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	• Firm has General tablet section as mentioned in the submitted GMP certificate. • Approved in MHRA as uncoated while initially the firm applied film- coated tablet.

		• Now, the firm has revised the applied formulation according to the reference and has submitted the requisite fees for revision of formulation i.e. Rs. 5000/- . • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1360.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zeptin- M 50/500mg Tablets
	Composition	Each film- coated tablet contains: Sitagliptin as Phosphate Monohydrate……..…50mg Metformin HCl……500mg
	Diary No. Date of R & I & fee	Dy.No.3488 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	S- Gliptin Plus Tablets of M/s Barrett Hodgson 076344
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	Firm has General tablet section as mentioned in the submitted GMP certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1361.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zeptin M 50/1000mg Tablets
	Composition	Each film- coated tablet contains: Sitagliptin as phosphate monohydrate……...50mg Metformin HCl……..…1000mg
	Diary No. Date of R & I & fee	Dy.No.3490 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	S- Gliptin Plus Tablets of M/s Barrett Hodgson 076345
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	Firm has General tablet section as mentioned in the submitted GMP certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1362.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Duloxeta 30mg Capsule
	Composition	Each capsule (enteric- coated pellets) contains: Duloxetine HCl……...30mg
	Diary No. Date of R & I & fee	Dy.No.3489 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & Rs. 250/-

	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 30 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Dulan 30mg by M/s Hilton Pharma. (Reg.# 055447)
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	Firm has General tablet section as mentioned in the submitted GMP certificate. Source of pellets is M/s Vision Pharma and all the data related with pellets is submitted.
	Decision: Approved with innovators' specifications.	
1363.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Duloxeta 20mg Capsule
	Composition	Each cap enteric coated pellets contains: Duloxetine HCl…20mg
	Diary No. Date of R & I & fee	Dy.No 3485 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & as per sro
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Dulan 20mg Capsule of Hilton Pharma (Pvt.) Limited 055446
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	Firm has General tablet section as mentioned in the submitted GMP certificate. Source of pellets is M/s Vision Pharma and all the data related with pellets is submitted.
	Decision: Approved with innovators' specifications.	
1364.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zetapram Tablet 10mg
	Composition	Each tablet contains: Escitalopram as Oxalate….....10mg
	Diary No. Date of R & I & fee	Dy.No 3484 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	SSRI
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14' s & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA as film- coated tablet
	Me-too status	Escital Tablet Helix Pharma (Pvt.) Ltd; 061634
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	• Firm has General tablet section as mentioned in the submitted GMP certificate. • Approved in MHRA as film- coated while initially the firm applied uncoated tablet. • Now, the firm has revised the applied formulation according to the reference but has not submitted the requisite fees for revision of formulation. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1365.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, Plot # 494-A, Sundar Industrial Estate, Lahore.

	Brand Name + Dosage Form + Strength	Zetac 50mg Tablet
	Composition	Each enteric- coated tablet Contains: Diclofenac Sodium…50mg Misoprostol…200mcg
	Diary No. Date of R & I & fee	Dy.No.3486 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Arthopan of M/s Safe Pharma 061790
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	• Ratio of misoprostol is not being mentioned in the reply. • Firm has General tablet section as mentioned in the submitted GMP certificate.
	Decision: Deferred for clarification regarding Misoprostol ratio in the applied formulation.	
1366.	Name and address of manufacturer/ Applicant	M/s Zeta Pharmaceuticals, 494-A, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Zetac 75mg Tablet
	Composition	Each enteric- coated tablet contains: Diclofenac Sodium….....75mg Misoprostol….....200mcg
	Diary No. Date of R & I & fee	Dy.No.3487 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	2 x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Artho Plus Shaigan Pharma 063196
	GMP status	GMP certificate has been submitted on the basis of evaluation done on 25-10-2019.
	Remarks of the Evaluator[XIII]	Ratio of misoprostol is not being mentioned in the reply. Firm has General tablet section as mentioned in the submitted GMP certificate.
	Decision: Deferred for clarification regarding Misoprostol ratio in the applied formulation.	
1367.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Repram 10mg Tablet
	Composition	Each film- coated tablet contains: Escitalopram as Oxalate….10mg
	Diary No. Date of R & I & fee	Dy.No.11438 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	SSRIs/ Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Escital Tablet Helix Pharma (Pvt.) Ltd;061634
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2% overages in our formulation for the safety of our products."

		• For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1368.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Sitametin 50/ 500mg Tablet
	Composition	Each film- coated Tablet Contains: Sitagliptin as Phosphate Monohydrate …….50mg Metformin HCl……...….500mg
	Diary No. Date of R & I & fee	Dy.No.11442 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	S- Gliptin Plus Tablets of M/s Barrett Hodgson 076344
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The applied formulation is non- pharmacopoeial. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	DecisionRegistration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1369.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Sitametin 50/ 1000mg Tablet
	Composition	Each film- coated Tablet Contains: Sitagliptin as Phosphate Monohydrate …….50mg Metformin HCl……...…1000mg
	Diary No. Date of R & I & fee	Dy.No.11424 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	S- Gliptin Plus Tablets of M/s Barrett Hodgson 076345
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The applied formulation is non- pharmacopoeial. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1370.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Montekal 10mg Chewable Tablet
	Composition	Each Chewable Tablet Contains: Montelukast as Sodium…10mg
	Diary No. Date of R & I & fee	Dy.No.11436 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019

	Pharmacological Group	Leukotriene Receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's & Rs. 24/- per tablet
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed as chewable tablet (4 & 5mg are available)
	Me-too status	Montekast 10mg Tablets of M/s Global Pharmaceutical, Industrial Triangle, Kahuta Road 032154
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • Could not be confirmed internationally as chewable tablet. • On applying initially as chewable tablet, firm replies: A clerical mistake occurs in our applied application of Montelukast Sodium 10mg chewable tablets but actually, we have applied for Montelukast Sodium 10mg film- coated tablet which has now been corrected in revised master formulation. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Confirmation of required manufacturing facility /section from Licensing Division.** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1371.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Tatinid 500mg Tablet
	Composition	Each film- coated tablet contains: Tinidazole….....500mg
	Diary No. Date of R & I & fee	Dy.No.11439 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tinidazole 500mg tablet of PDH Lahore 009757
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified. • The applied formulation is non- pharmacopoeial.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1372.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK.
	Brand Name + Dosage Form + Strength	Taneprox 500mg Tablet
	Composition	Each film-coated tablet contains: Naproxen sodium eq. to Naproxen……..500mg
	Diary No. Date of R & I & fee	Dy.No.11423 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAIDs

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as uncoated
	Me-too status	Naprox Tab 500mg of M/s Pharmedic Lahore
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The official monograph is in USP. • On applying initially as film-coated tablet, firm replies: A clerical mistake occurs in our applied application of Naproxen sodium 10mg film-coated tablets but actually, we have applied for Naproxen sodium 10mg uncoated tablet which has now been corrected in revised master formulation. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1373.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Tablinez 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…….600mg
	Diary No. Date of R & I & fee	Dy.No 11422 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved as film- coated
	Me-too status	Linez 600mg Tablet of M/s Nexus Pharma (Pvt.)Ltd Korangi Industrial Area, Karachi (Reg. # 061309)
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• In applied master formulation, Azithromycin is applied whch the firm says says is due to clerical mistake. • Total applied composition was different than the applied one. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following clarifications: • **Form 5 for correction in composition with fee.** • **Total applied composition was different than the applied one.** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1374.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Codofen Tablets 20mg/ 200mg
	Composition	Each film- coated Tablet Contains: Codeine Phosphate……..…20mg Ibuprofen……..200mg

	Diary No. Date of R & I & fee	Dy.No.11421 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Brufen Plus of M/s Abbott
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98- 99% to 101- 102%. Therefore, we are adding 2% overages in our formulation for the safety of our products." • International reference could not be confirmed. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred For Following: • **Stability Data for overage used in formulation.** • **Approval Status Reference Regulatory Authorities.** • **Registration Board Referred to QA & LT Division for updated GMP Status of the firm** • **Narcotic Section Approval By Licensing Division.**	
1375.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Tapride 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R & I & fee	Dy.No.11441dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 12's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by AIFA (Italy)
	Me-too status	Caresul 50mg Tablet of Tabros Pharma (Pvt.) Ltd Karachi 066757
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The applied formulation is non- pharmacopoeial. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1376.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Seizugab 100mg Capsule
	Composition	Each Capsule Contains: Gabapentin……100mg
	Diary No. Date of R & I & fee	Dy.No.11444 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Gabaplus Capsule 100mg of M/s Platinum Pharmaceuticals Qasim Karachi 035664
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2% overages in our formulation for the safety of our products." • The official monograph is available in USP. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1377.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Seizugab 300mg Capsule
	Composition	Each Capsule Contains: Gabapentin……300mg
	Diary No. Date of R & I & fee	Dy.No.11443 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Gabapa 300mg Capsule of M/s Farm Aid Group Hattar 056721
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2% overages in our formulation for the safety of our products." • The official monograph is available in USP. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1378.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Cangio- A 5/80mg Tablet
	Composition	Each film- coated tablet contains: Amlodipine besylate eq. to Amlodipine…… 5mg Valsartan……80mg
	Diary No. Date of R & I & fee	Dy.No.11429 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Angiotensin- II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's, 2x 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as film coated

	Me-too status	Exforge 5/ 80mg film- coated tablets of M/s Novartis Pharma (Pakistan) Limited, Karachi (Reg. # 047569)
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1379.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Cangio- A 5/160mg Tablet
	Composition	Each film- coated Tablet Contains: Amlodipine as Besylate……...5mg Valsartan……..160mg
	Diary No. Date of R & I & fee	Dy.No.11428 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Angiotensin- II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 14's, 2x 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge 5/ 160mg film- coated tablets of M/s Novartis Pharma (Pakistan) Limited, Karachi (Reg. # 047570)
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1380.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Spaslax 3mg Tablet
	Composition	Each Tablet Contains: Oxybutynin HCl……...3mg
	Diary No. Date of R & I & fee	Dy.No.11446 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Urologicals
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Oxitrin Tablets 3mg of Dr. Raza Pharma (Pvt.) Ltd, 44-C, Industrial Estate Hayatabad, Peshawar 023896
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2% overages in our formulation for the safety of our products." • The official monograph is available in BP.

		• For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following: • **Stability Data for overage used in formulation** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1381.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Moximil 400mg Tablet
	Composition	Each film- coated Tablet Contains: Moxifloxacin HCl……...400mg
	Diary No. Date of R & I & fee	Dy.No.11437 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Moxifo 400mg Tablet of M/s Tabros Pharma, Karachi 048764
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2% overages in our formulation for the safety of our products." • The official monograph is available in USP. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following: • **Stability Data for overage used in formulation** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1382.	Name and address of manufacturer/ Applicant	M/s Lawari International Pharmaceuticals, Valley Road, Gul KADU Saidu Sharif Swat, KPK
	Brand Name + Dosage Form + Strength	Aspidogrel 75mg/75mg Tablet
	Composition	Each film- coated tablet contains: Clopidogrel as Hydrogen sulphate ……...75mg Aspirin……...75mg
	Diary No. Date of R & I & fee	Dy.No.11425 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- thrombotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA; Australia
	Me-too status	Clopid ASP 75 tablet of M/s Ferozsons Labs Amangarh, Nowshera. 043643
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• Justification given by firm for 2% overage is as follows: "As per official monograph, the limit of raw material is as 98-99% to 101-102%. Therefore, we are adding 2%

		overages in our formulation for the safety of our products." • The applied formulation is non- pharmacopoeial. • For GMP inspection report, firm clarifies that its inspection is pending due to current situation of Covid-19 and unavailability of Area FID-III. • Section needs to be verified.
	Decision: Deferred for following reasons: • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.** • **Clarification of manufacturing outline in the light of innovator product and requisite facility.**	
1383.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rickdil tablet 0.25mcg
	Composition	Each film- coated tablet contains: Alfacalcidol……..……...0.25mcg
	Diary No. Date of R & I & fee	Dy.No.10906 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Vitamin- D and analogues
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA; Japan Approved as uncoated tablet
	Me-too status	Bonedol 0.25mcg Tablets of M/s Pharmevo, Karachi 036614
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. Initially, firm had applied uncoated tablet. • Now, the firm has revised its formulation according to the reference as uncoated tablets with submission of Rs. 5000/- requisite fees.
	Decision: Approved.	
1384.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rickdil tablet 0.5mcg
	Composition	Each film- coated tablet contains: Alfacalcidol……..…….....0.5mcg
	Diary No. Date of R & I & fee	Dy.No.10905 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Vitamin- D and analogues
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA; Japan Approved as uncoated tablet
	Me-too status	Bonedol 0.5Mcg Tablets Pharmevo, Karachi 036615
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. Initially, firm had applied uncoated tablet. • Now, the firm has revised its formulation according to the reference as uncoated tablets with submission of Rs. 5000/- requisite fees.
	Decision: Approved.	
1385.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.

	Brand Name + Dosage Form + Strength	Rickdil tablet 1mcg
	Composition	Each film- coated tablet contains: Alfacalcidol……..……...1mcg
	Diary No. Date of R & I & fee	Dy.No.10907 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Vitamin- D and analogues
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA; Japan Approved as uncoated tablet
	Me-too status	Bonedol 1Mcg Tablets Pharmevo, Karachi 035538
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. Initially, firm had applied uncoated tablet. • Now, the firm has revised its formulation according to the reference as uncoated tablets with submission of Rs. 5000/- requisite fees.
	Decision: Approved with innovators' specifications.	
1386.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Desil Tablet 5mg
	Composition	Each film coated tablet contains: Desloratadine ……..…5mg
	Diary No. Date of R & I & fee	Dy.No.10912 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Deslort 5mg Tablet of M/s Panacea Pharmaceuticals Rawat, Islamabad 056332
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1387.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Reonate Tablet 10mg
	Composition	Each Tablet Contains: Alendronate Sodium eq. to Alendronic Acid……10mg
	Diary No. Date of R & I & fee	Dy.No.10917 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Bisphosphonate
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	4's, 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Alendroflex 10mg Tablets of M/s Novins International, Karachi 042386
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.

	Decision: Approved.	
1388.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Reonate Tablet 70mg
	Composition	Each tablet contains: Alendronate Sodium eq. to Alendronic Acid……70mg
	Diary No. Date of R & I & fee	Dy.No.10918 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Bisphosphonate
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	4's, 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Alendroflex 70mg tablets of Novins International, Karachi 042387
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1389.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova Tablet 250mg
	Composition	Each film- coated tablet contains: Ciprofloxacin as HCl ….250mg
	Diary No. Date of R & I & fee	Dy.No.10890 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoro- quinolone
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Medociprin 250mg tablet of M/s Medochemie Cyprus Alina Combine Karachi 012162
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1390.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova Tablet 500mg
	Composition	Each film- coated tablet contains: Ciprofloxacin as HCl…...500mg
	Diary No. Date of R & I & fee	Dy.No.10891 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoro- quinolone
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ciproxin 500 tablet of M/s Bayer Karachi 013329
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	

1391.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova XR Tablet 500mg
	Composition	Each extended- release tablet contains: Ciprofloxacin as HCl……500mg
	Diary No. Date of R & I & fee	Dy.No.10892 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoro- quinolone
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as bi-layered **tablets consisting of an immediate-release layer and an erosion-matrix type controlled- release layer.**
	Me-too status	Ciproscot XR Tablets of M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP. • **Innovator formulation: CIPRO XR tablets are coated, bilayer tablets consisting of an immediate-release layer and an erosion- matrix type controlled-release layer. The tablets contain a combination of two types of ciprofloxacin drug substance, ciprofloxacin hydrochloride and ciprofloxacin betaine (base).** • **Initially, firm had applied extended- release tablet. Now, revision of formulation as per innovator is done by the firm with submission of Rs. 5000/- fees and evidence of bilayered machine has also been submitted.**
	Decision: Deferred for further deliberation upon manufacturing outine of applied formulation in the light of innovator's product.	
1392.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova XR Tablet 1000mg
	Composition	Each extended- release tablet contains: Ciprofloxacin as HCl……..1000mg
	Diary No. Date of R & I & fee	Dy.No.10893 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoro- quinolone
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as bi-layered **tablets consisting of an immediate- release layer and an erosion- matrix type controlled- release layer.**
	Me-too status	Makcip XR Tablets of M/s Makson Pharmaceuticals Islamabad 070014
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.

		• **Innovator formulation: CIPRO XR tablets are coated, bilayer tablets consisting of an immediate-release layer and an erosion- matrix type controlled-release layer. The tablets contain a combination of two types of ciprofloxacin drug substance, ciprofloxacin hydrochloride and ciprofloxacin betaine (base).** • **Initially, firm had applied extended- release tablet. Now, revision of formulation as per innovator is done by the firm with submission of Rs. 5000/- fees and evidence of bilayered machine has also been submitted.**
	Decision: Deferred for further deliberation upon manufacturing outine of applied formulation in the light of innovator's product.	
1393.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rheuma 10mg Tablet
	Composition	Each film- coated tablet contains: Leflunomide……..…..10mg
	Diary No. Date of R & I & fee	Dy.No.10903 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Lefluno Tablet of M/s Caraway Pharmaceuticals, Islamabad 050062
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1394.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rheuma 20mg Tablet
	Composition	Each film- coated tablet contains: Leflunomide…….……..20mg
	Diary No. Date of R & I & fee	Dy.No.10904 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Lefluno Tablet of M/s Caraway Pharmaceuticals, Islamabad. 050063
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1395.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Dexofin Tablet 200mg
	Composition	Each film- coated tablet contains: Dexibuprofen……...200mg

	Diary No. Date of R & I & fee	Dy.No.10911 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Dexib 200mg Tablet of M/s Tabros Pharmaceutical Karachi 067491
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1396.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Dexofin 300mg Tablet
	Composition	Each film- coated tablet contains: Dexibuprofen……...300mg
	Diary No. Date of R & I & fee	Dy.No.10897 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Dexib 300mg Tablet of M/s Tabros Pharmaceutical Karachi 067493
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1397.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Sofen Ophthalmic Ointment 10%/ 0.2%
	Composition	Each gram contains: Sulfacetamide sodium……...100mg Prednisolone acetate……..2mg
	Diary No. Date of R & I & fee	Dy.No.10899 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Corticosteroids and anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3.5gx 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Predmide Ophthalmic Ointment of M/s Remington Pharmaceutical Industries, Lahore 026903
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	Cream/ Ointment/ Gel (Antibiotics with steroids) section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Deferred for confirmation of separate dispensing booth as per decision of Licensing Board.	
1398.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Raygil Infusion 500mg/100ml

	Composition	Each 100ml contains: Metronidazole……..500mg
	Diary No. Date of R & I & fee	Dy.No.10898 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Metrida I.V Infusion of M/s Zafa Pharmaceuticals Laboratories (Pvt.) Ltd Baluchistan 026232
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1399.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Raydex- T Ophthalmic ointment
	Composition	Each gram contains: Dexamethasone……..…0.3% 3mg Tobramycin……..0.1% 1mg
	Diary No. Date of R & I & fee	Dy.No.10901 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Corticosteroid /Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tobradex Ointment of M/s Ali Gohar & Co Karachi 017041
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	Cream/ Ointment/ Gel (Antibiotics with steroids) section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Deferred for confirmation of separate dispensing booth as per decision of Licensing Board.	
1400.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Raymox 0.5% Eye Ointment
	Composition	Each gram contains: Moxifloxacin as HCl …….. 5mg (0.5%)
	Diary No. Date of R & I & fee	Dy.No.10900 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoroquinolone Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed as ointment
	Me-too status	Ocumox of M/s Remington Pharmaceutical Industries (Pvt.) Ltd., Lahore 069155
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	Cream/ Ointment/ Gel (Antibiotics with steroids) section is available in the firm as mentioned in the submitted GMP inspection report. Non- pharmacopoeial.

		Reference could not be confirmed as ointment.
	Decision: Deferred for following reasons: • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
1401.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova 125mg/ 5ml Powder for suspension
	Composition	Each 5ml contains: Ciprofloxacin eq. to Ciprofloxacin……..125mg
	Diary No. Date of R & I & fee	Dy.No.10895 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Hiflox 125mg/5ml Dry Suspension of M/s Hilton Pharma (Pvt.) Limited; Korangi, Karachi 067498
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Dry powder suspension (Antibiotic) section is available in the firm as mentioned in the submitted GMP inspection report. • **Source of granules is Zhejiang Jingxi Pharmaceutical, China whose CoA copy is submitted.** • **Registration Board in its 269th meeting decided as follows:** **Keeping in view the following statement written in Qualitative and quantitative composition "2.5 ml suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age,.Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA.**
	Decision: Approved with innovators' specifications.	
1402.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova 250mg/ 5ml Powder for suspension
	Composition	Each 5ml contains: Ciprofloxacin eq. to Ciprofloxacin……..250mg
	Diary No. Date of R & I & fee	Dy.No.10894 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ciplet 250mg/5ml Suspension of M/s Indus Pharma Karachi 073479
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.

	Remarks of the Evaluator[XIII]	Dry powder suspension (Antibiotic) section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
1403.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova Infusion 200mg/100ml
	Composition	Each 100ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin……..200mg
	Diary No. Date of R & I & fee	Dy.No.10888 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	100ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Caralox Infusion of M/s Caraway Pharmaceuticals, Islamabad 050044
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1404.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S- 58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ciprova DS 400mg/ 100ml Infusion
	Composition	Each 100ml Contains: Ciprofloxacin HCl……...400mg
	Diary No. Date of R & I & fee	Dy.No.10889 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Novidat DS 400mg/100ml Infusion Sami Pharmaceutical, Karachi 042270
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report. Reference could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.	
1405.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rayvir 250mg Infusion I/V
	Composition	Each ml contains: Acyclovir sodium eq. to Acyclovir…….250mg
	Diary No. Date of R & I & fee	Dy.No.10915 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10ml vial & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aciclovir Sandoz IV Infusion Aciclovir 250mg powder for injection vial, TGA: Australia Approved
	Me-too status	Zovirax Infusion of M/s Glaxo Smith Kline Karachi 009975

	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1406.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rayvir 500mg Infusion I/V
	Composition	Each ml contains: Acyclovir sodium eq. to Acyclovir……..500mg
	Diary No. Date of R & I & fee	Dy.No.10916 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	20ml vial & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aciclovir Sandoz IV Infusion Aciclovir 500mg powder for injection vial, TGA; Australia Approved
	Me-too status	Acyclovir infusion 500mg of M/s Abbott (021397)
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report. • 25mg is written in the applied composition while 500mg is applied.
	Decision: Deferred for clarification as 25mg is written in the applied composition while 500mg is applied.	
1407.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ray- D Injection 5mg/ml
	Composition	Each 1ml contains: Cholecalciferol -Vit D3……5mg
	Diary No. Date of R & I & fee	Dy.No.10913 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Vitamin- D and analogue
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1ml x 5's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Get- D 5mg/ml Injection of M/s Getz Pharma (Pvt.) Ltd. Karachi 067547
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
1408.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S- 58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Rayvir 200mg Tablet
	Composition	Each film- coated tablet contains: Acyclovir sodium eq. to Acyclovir…….200mg
	Diary No. Date of R & I & fee	Dy.No.10914 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as dispersible film- coated tablet

	Me-too status	Cycloz Tablet of M/s Highnoon Lahore 012392
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • In reference, it is as dispersible film- coated tablet.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is dispersible film- coated tablet, while the applied drug is film-coated tablet.	
1409.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Roxib Tablets 60mg
	Composition	Each film- coated tablet contains: Etoricoxib……..…...60mg
	Diary No. Date of R & I & fee	Dy.No.10908 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoricox 60mg Tablet of Kaizen Pharma Karachi 076226
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1410.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Reonate- D Tablet 70mg/ 2800 IU
	Composition	Each Tablet Contains: Alendronate as Sodium eq. to Alendronic sodium….70mg Cholecalciferol……..……..…2800IU (70mcg)
	Diary No. Date of R & I & fee	Dy.No.10902 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Drugs for treatment of bone diseases/ Bisphosphonate
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	4's, 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alonate- D of M/s Neo Medix Islamabad 066467
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1411.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Artichin Injection 4mg/2ml I/M
	Composition	Each 2ml ampoule contains: Thiocolchicoside……..4mg
	Diary No. Date of R & I & fee	Dy.No.10910 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Thiocol 4mg/ 2ml Injection of M/s Ray Pharma (Pvt.) Ltd., Karachi 066712
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General liquid injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
1412.	Name and address of manufacturer/ Applicant	M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Artichin 4mg Capsule
	Composition	Each capsule contains: Thiocolchicoside…….4mg
	Diary No. Date of R & I & fee	Dy.No.10909 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Muscle relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Thiocol 4mg Capsule of M/s Ray Pharma (Pvt.) Ltd., Karachi 066711
	GMP status	Last GMP inspection was conducted on 14-03-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	General capsule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
1413.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ezone Injection 1000mg
	Composition	Each vial contains: Cefoperazone as Sodium…….……...….500mg Sulbactam as Sodium…….……....…500mg
	Diary No. Date of R & I & fee	Dy.No.10977 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Cephalosporin/ Beta Lactam Inhibitor
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1 vial dry substance + 5ml ampoule water for injection & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Sulperazon Injection by Pfizer Inc. PMDA Approved**
	Me-too status	Ectafin Injection 1gm I/V of M/s Hi-Medic Pharmaceuticals (Pvt.) Ltd, 19- KM link Multan Road, Lahore 080028
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.

	Remarks of the Evaluator[XIII]	• Manufacturer firm has Dry powder injection Cephalosporin section as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted.
	Decision: Deferred for following: • **Number of sections of applicant needs to be submitted.** • **Number of approved drugs of applicant on contract basis needs to be submitted.**	
1414.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Maxpime 500mg Injection I/V, I/M
	Composition	Each Vial Contains: Cefepime HCl with L- Arginine……..500mg
	Diary No. Date of R & I & fee	Dy.No.10981 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved as Cefepime hydrochloride monohydrate equivalent to Cefepime 500 mg, powder for injection
	Me-too status	Cefstar Injection 500mg of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, S.I.T.E, Karachi 030953
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes: Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • Revise the label claim and master formulation as Cefepime hydrochloride monohydrate equivalent to Cefepime as in TGA, Australia. **Correction along with adjustment of its weight as per salt factor needs to be submitted.** • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Volume of injection and pack size needs to be submitted.
	Decision: Deferred for following: • **Revision of label claim alongwith adjustment of weight of salt factor in master formulation**	

	• **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Eros pharmaceuticals pvt. Ltd., Karachi.**	
1415.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Maxpime 1000mg Injection
	Composition	Each Vial Contains: Cefepime HCl with L- Arginine……....1000mg
	Diary No. Date of R & I & fee	Dy.No.10982 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved as Cefepime hydrochloride monohydrate equivalent toCefepime 1g, powder for injection
	Me-too status	Cefstar Injection 1g of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, S.I.T.E, Karachi. 030954
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes: Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • Revise the label claim and master formulation as Cefepime hydrochloride monohydrate equivalent to Cefepime as in TGA, Australia. **Correction along with adjustment of its weight as per salt factor needs to be submitted.** • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Volume of injection and pack size needs to be submitted.
	Decision: Deferred for following: • **Revision of label claim alongwith adjustment of weight of salt factor in master formulation** • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s eros pharmaceuticals pvt. Ltd., Karachi.**	
1416.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ferofer Injection 100mg
	Composition	Each vial contains: Iron sucrose complex eq. to elemental iron…….100mg
	Diary No. Date of R & I & fee	Dy.No.10974 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Anti- anaemic

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA as single dose vial
	Me-too status	Ferotein- S Injection of M/s Getz Pharma, Karachi (Reg. # 055440)
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• Manufacturer firm has Liquid ampoule General injection section as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Ampoule or vial what is applied not confirmed. • Volume of injection and pack size needs to be submitted.
	Decision: Deferred for following: **• Number of products already approved on contract manufacturing.** **• Number of sections approved for M/s Eros pharmaceuticals pvt. Ltd., Karachi.** **• Submission of details of primary packaging whether vial or ampoule.**	
1417.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	P- Zac Infusion 40mg (powder for infusion)
	Composition	Each amber glass vial contains: Pantoprazole……40mg
	Diary No. Date of R & I & fee	Dy.No.10978 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	PPI
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	Amber glass vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zentro Injection of M/s Bosch, Karachi 045388
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma:

		Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• Approved in MHRA as Pantoprazole as sodium sesquihydrate • General infusion section is available in the manufacturers firm as mentioned in the submitted DML. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Strength of infusion is not mentioned. • Volume of injection and pack size needs to be submitted.
	Decision: Deferred for following: **• Revision of salt form as per reference product.** **• Number of products already approved on contract manufacturing.** **• Number of sections approved for M/s Eros pharmaceuticals pvt. Ltd., Karachi**	
1418.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Esma Infusion 40mg I/M
	Composition	Each vial Contains: Esomeprazole as Sodium……..40mg
	Diary No. Date of R & I & fee	Dy.No 10975 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	PPI
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as lyophilized powder
	Me-too status	Somezol of M/s Bosch 045386
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• General infusion section is available in the manufacturers firm as mentioned in the submitted DML. • The applied drug is non- pharmacopoeial. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Volume of injection and pack size needs to be submitted. • MHRA Approved as lyophilized powder.
	Decision: Deferred for following:	

	• **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Eros pharmaceuticals pvt. Ltd., Karachi.**	
1419.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Ezone Injection 2000mg
	Composition	Each Vial Contains: Cefoperazone Sodium……..…1000mg Sulbactam Sodium……1000mg
	Diary No. Date of R & I & fee	Dy.No 10976 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Cephaolsporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia**
	Me-too status	Q- Bact 2gm Injection of High- Q Karachi 061170
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• Manufacturer firm has Dry powder injection (Cephalosporin) section as mentioned in the submitted GMP inspection report. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Pack size needs to be submitted. • The official monograph for the applied formulation is available in JP. • Cefoperazone sodium eq. to Cefoperazone is approved in reference. • Sulbactam sodium eq. to Sulbactam is approved in reference.
	Decision: Deferred for following: • **Revision of label claim as per reference product** • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s eros pharmaceuticals pvt. Ltd., Karachi.**	
1420.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Vit-3 Injection 5mg
	Composition	Each ampoule contains: Cholecalciferol……...5mg (200,000IU)
	Diary No. Date of R & I & fee	Dy.No 10980 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019

	Pharmacological Group	Vitamin- D and analogue
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Get- D 5mg/ml Injection of M/s Getz Pharma (Pvt.) Ltd. Karachi 067547
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma: Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• Manufacturer firm has Liquid ampoule General injection section as mentioned in the submitted DML. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Volume of injection and pack size needs to be submitted. • The applied drug is non- pharmacopoeial.
	Decision: Deferred for following: • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s eros pharmaceuticals pvt. Ltd., Karachi.**	
1421.	Name and address of manufacturer/ Applicant	M/s Eros Pharmaceuticals Pvt. Ltd., Plot # 94-95, Sector 23, Korangi Industrial Area Karachi. Contract Manufacturer M/s Mediate Pharmaceutical Pvt. Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	K- Cort 40mg/ml Injection I/V
	Composition	Each ml contains: Triamcinolone Acetonide…40mg
	Diary No. Date of R & I & fee	Dy.No 10979 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1 vialx 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	*USFDA Approved as injectable suspension*
	Me-too status	M-Kort 40mg /ml Injection of M/s Mediate Pharmaceuticals, Karachi 057916
	GMP status	M/s Eros Pharma: Last GMP inspection was conducted on 11-12-2018 and the report concludes : Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for thorough cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production. M/s Mediate Pharma:

		Last GMP inspection was conducted on 02-04-2019 and the report concludes acceptable level of good compliance.
	Remarks of the Evaluator[XIII]	• Manufacturer firm does not have steroidal injection section. • The official monograph for the applied formulation is available in USP. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Volume of injection and pack size needs to be submitted. • NOT FOR INTRAVENOUS USE (For Intramuscular or Intra-articular Use Only). • USFDA Approved as injectable suspension while is applied as infusion.
	Decision: Deferred for following: • **Revision of dosage form as per reference formulation.** • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s eros pharmaceuticals pvt. Ltd., Karachi.**	
1422.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt. Ltd, 138-Nowshera Industrial, Risalpur, KPK. Contract manufactured by M/s Bio Labs Pvt. Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Ceftam 1g Injection I/V
	Composition	Each vial contains: Cefoperazone sodium eq. to Cefoperazone……500mg Sulbactam sodium eq. to Sulbactam……500mg
	Diary No. Date of R & I & fee	Dy.No.4229 dated 30-02-2019 Rs.50,000/- Dated 29-02-2019
	Pharmacological Group	Cephalosporin/ Beta Lactam Inhibitor
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	1x1 vial & As per SRO
	Approval status of product in Reference Regulatory Authorities	**Sulperazon Injection of M/s Pfizer PMDA; Japan Approved**
	Me-too status	Ectafin Injection 1gm I/V of M/s Hi- Medic Pharmaceuticals (Pvt.) Ltd, Multan Road, Lahore 080028
	GMP status	M/s Alen Pharmaceuticals: Last GMP inspection was conducted on 15-01-2020 and the report concludes to *Suspend Production activities in all sections.* M/s Bio Labs: last GMP inspection was conducted on 25-05-2019 and the report concludes grant of certificate of GMP Issued on 25-05-2019.
	Remarks of the Evaluator[XIII]	• Manufacturer firm has Dry vial Cephalosporin section as mentioned in the submitted GMP certificate. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • M/s Alen Pharma has its production activities suspended according to latest GMP report. • The official monograph for the applied formulation is available in JP.

		• Cefoperazone sodium eq. to Cefoperazone is approved in reference. • Sulbactam sodium eq. to Sulbactam is approved in reference.
	Decision: Deferred for following: • **Revision of label claim as per reference formulation.** • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Alen pharmaceuticals pvt. Ltd., Risalpur** • **DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.**	
1423.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt. Ltd, 138-Nowshera Industrial, Risalpur, KPK. Contract manufacturer M/s Bio Labs Pvt. Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Ceftam 2g Injection
	Composition	Each Vial Contains: Cefoperazone sodium eq to Cefoperazone……1g Sulbactam sodium eq to Sulbactam……..1g
	Diary No. Date of R & I & fee	Dy.No. 4230 dated 30-02-2019, Rs.50,000/- Dated 29-02-2019
	Pharmacological Group	Cephalosporin/ Beta Lactam Inhibitor
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia**
	Me-too status	**Ectafin Injection 2gm I/V of M/s Hi-Medic Pharmaceuticals (Pvt.) Ltd. Reg. No.** 080027
	GMP status	M/s Alen Pharmaceuticals: Last GMP inspection was conducted on 15-01-2020 and the report concludes to *Suspend Production activities in all sections.* M/s Bio Labs: last GMP inspection was conducted on 25-05-2019 and the report concludes grant of certificate of GMP Issued on 25-05-2019.
	Remarks of the Evaluator[XIII]	• Manufacturer firm has Dry vial Cephalosporin section as mentioned in the submitted GMP certificate. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • M/s Alen Pharma has its production activities suspended according to latest GMP report. • The official monograph for the applied formulation is available in JP. • Cefoperazone sodium eq. to Cefoperazone is approved in reference. • Sulbactam sodium eq. to Sulbactam is approved in reference.
	Decision: Deferred for following: • **Revision of label claim as per reference formulation.** • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Alen pharmaceuticals pvt. Ltd., Risalpur** • **DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.**	
1424.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd, 138-Nowshera Industrial, Risalpur, KPK. Contract manufacturer

		M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Balmin 500mcg Injection
	Composition	Each ampoule 1ml contains: Mecobalamin.....…500mcg
	Diary No. Date of R & I & fee	Dy.No.4227 dated 30-02-2019 Rs.50,000/- Dated 29-02-2019
	Pharmacological Group	**Vitamin- B**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	Ampoule of 1mlx 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA; Japan Approved
	Me-too status	Mecobal Injection 500mcg of M/s Nabiqasim Industries (Pvt) Ltd, Korangi Industrial Area, Karachi 030288
	GMP status	M/s Alen Pharmaceuticals: Last GMP inspection was conducted on 15-01-2020 and the report concludes to *Suspend Production activities in all sections.* M/s Bio Labs: last GMP inspection was conducted on 25-05-2019 and the report concludes grant of certificate of GMP Issued on 25-05-2019.
	Remarks of the Evaluator[XIII]	• M/s Alen Pharma has its production activities suspended according to latest GMP report. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Manufacturer has General Ampoule section according to the submitted GMP certificate. • The applied drug is non- pharmacopoeial.
	Decision: Deferred for following: • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Alen pharmaceuticals pvt. Ltd., Risalpur** • **DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.**	
1425.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt. Ltd, 138-Nowshera Industrial, Risalpur, KPK. Contract manufacturer M/s Bio Labs Pvt. Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Vamin- D3 5mg Injection I/M
	Composition	Each 1ml contains: Cholecalciferol-Vitamin D3……5mg (**200,000 IU)**
	Diary No. Date of R & I & fee	Dy.No.4228 dated 30-02-2019 Rs.50,000/- Dated 29-01-2019
	Pharmacological Group	**Vitamin- D analogue**
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1mlx 1's (ampoule) & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Vitamin D3 Good 200,000 IU / 1 ml I/M solution for injection (ANSM, France)**
	Me-too status	**Get-D 5mg/ml Injection of M/s** Getz Pharma (Pvt.) Ltd. Korangi Industrial Area Karachi 067547
	GMP status	M/s Alen Pharmaceuticals: Last GMP inspection was conducted on 15-01-2020 and the report concludes to *Suspend Production activities in all sections.* M/s Bio Labs: last GMP inspection was conducted on 25-05-2019 and the report concludes grant of certificate of GMP Issued on 25-05-2019.

	Remarks of the Evaluator[XIII]	• M/s Alen Pharma has its production activities suspended according to latest GMP report. • No. of sections of applicant needs to be submitted. • No. of approved drugs on contract basis needs to be submitted. • Section approval letter of applicant needs to be submitted. • Manufacturer has General Ampoule section according to the submitted GMP certificate.
	Decision: Deferred for following: • **Number of products already approved on contract manufacturing.** • **Number of sections approved for M/s Alen pharmaceuticals pvt. Ltd., Risalpur** • **DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.**	
1426.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3, Islamabad.
	Brand Name + Dosage Form + Strength	Toricox 60mg tablet
	Composition	Each film- coated tablet contains: Etoricoxib……...60mg
	Diary No. Date of R & I & fee	Dy.No.1234 dated 10-01-2019 Rs.20,000/- Dated 10-01-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoricox 60mg Tablet of M/s Kaizen Pharma, Kar 076226
	GMP status	**Last GMP inspection was conducted on 23-7-2018 and the report concludes that the firm was found in satisfactory compliance with GMP guidelines.**
	Remarks of the Evaluator[XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1427.	Name and address of manufacturer/ Applicant	M/s Venus Pharma, 23 km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Furosa-V 10mg/ml Injection I/M, I/V
	Composition	Each ml contains: Furosemide……10mg
	Diary No. Date of R & I & fee	Dy.No.2043 dated 16-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Diuretics
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3's, 5's,10's, 50's ampoules & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Furosemide Injection of M/s Abbott Karachi 011759
	GMP status	Last GMP inspection was conducted on 09-07-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	Liquid injection vial/ ampoule section is available in the firm as mentioned in the submitted GMP certificate. The official monograph for the applied formulation is available in USP.
	Decision: Approved with innovators' specifications.	
1428.	Name and address of manufacturer/ Applicant	M/s News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	New- Lac Injection 30mg/ml
	Composition	Each ml contains: Ketorolac Trometamol……..30mg

	Diary No. Date of R & I & fee	Dy.No.2688 dated 21-01-2019 Rs.20,000/- Dated 21-01-2019
	Pharmacological Group	**NSAIDs**
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5x 1ml ampoules & Rs. 750/- per pack
	Approval status of product in Reference Regulatory Authorities.	Toradol Injection of Atnahs Pharma, UK (MHRA Approved)
	Me-too status	**Toralac Injection 30mg/ml of M/s Vision Pharma (Reg. #050290)**
	GMP status	**Last GMP Inspection of M/s News Pharma was conducted on 26-4-2018 as a result of which GMP certificate is provided.**
	Remarks of the Evaluator[XIII]	**General liquid injectable section is available in the firm as mentioned in the submitted GMP certificate.**
	Decision: Approved.	
1429.	Name and address of manufacturer/ Applicant	M/s Invictus Pharmaceuticals, Plot No. 21, 26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Invilox tablet 400mg
	Composition	Each film- coated tablet contains: Moxifloxacin HCl eq. to Moxifloxacin……...…400mg
	Diary No. Date of R & I & fee	Dy.No.1718 dated 14-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 5's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Moxiflox 400mg Tablets of M/s Ideal Pharma 054123
	GMP status	**Last GMP inspection was conducted on 13-11- 2018, The panel recommended the grant of** DML.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1430.	Name and address of manufacturer/ Applicant	M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Stron 4mg Tablets
	Composition	Each film- coated Tablet Contains: Ondansetron HCl Dihydrate Eq. to Ondansetron.....4mg
	Diary No. Date of R & I & fee	Dy.No.2915 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti- emetic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**USFDA Approved**
	Me-too status	**Ondonix 4mg tablet M/s Genix Pharma** 081545
	GMP status	**Last GMP inspection was conducted on 13-11- 2018, The panel recommended the grant of** DML.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1431.	Name and address of manufacturer/ Applicant	M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Stron 8mg Tablets
	Composition	Each film- coated Tablet Contains: Ondansetron HCl Dihydrate Eq. to Ondansetron.....8mg
	Diary No. Date of R & I & fee	Dy.No.2916 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti- emetic

	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**USFDA Approved**
	Me-too status	**Ondonix 4mg Tablet M/s Genix Pharma** 081451
	GMP status	**Last GMP inspection was conducted on 13-11- 2018, The panel recommended the grant of** DML.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1432.	Name and address of manufacturer/ Applicant	M/s Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Pentol 40mg Capsule
	Composition	Each capsule contains: Enteric Coated Pellets of Pantoprazole Sodium Eq. to Pantoprazole……40mg
	Diary No. Date of R & I & fee	Dy.No.1736 dated 14-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	PPIs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 20's, 28's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nixpro 40mg Capsule of M/s Indus Pharma, Karachi 053492
	GMP status	Last GMP inspection was conducted on 13-11- 2018. The panel recommended the grant of **DML.**
	Remarks of the Evaluator[XIII]	• Reference could not be confirmed • All the data related to pellets was needed. • Initially, firm had applied capsules while now they have changed their applied dosage form from capsules to enteric- coated tablets with submission of 20,000 fees under deposit slip # 1925516 (12-05-2020). • Applied label claim is now: Each enteric- coated tablet contains: Pantoprazole……40mg • Tablets are ANSM; France Approved. • Me- too of tablets is: Kinzole Tablets of M/s Tagma Pharma (Pvt), Lahore 024212. • The official monograph for tablets is available in USP. • Form- 5, master formulation and all related documents have been revised as tablets.
	Decision: Approved with following label claim: **Each enteric coated tablet contains:** **Pantoprazole …….40mg**	
1433.	Name and address of manufacturer/ Applicant	M/s Invictus Pharmaceuticals, Plot No. 21, 26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Trobak Tablet 37.5mg/325 mg
	Composition	Each film- coated tablet contains: Tramadol HCl…….37.5mg Paracetamol……..325mg
	Diary No. Date of R & I & fee	Dy.No.1710 dated 14-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	USP

	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tramadoln Plus Tablet 37.5+325mg of M/s Akson Pharma 085459
	GMP status	**Last GMP inspection was conducted on 13-11- 2018, The panel recommended the grant of** DML.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1434.	Name and address of manufacturer/ Applicant	M/s Fozan Pharmaceutical, 36-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	Ether Plus tablet 80/480 mg
	Composition	Each tablet contains: Artemether……80mg Lumefantrine……480mg
	Diary No. Date of R & I & fee	Dy.No.4661 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	**Anti-malarial**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**WHO recommended formulation**
	Me-too status	**Artem -DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)**
	GMP status	Last GMP inspection was conducted on 25-05-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in **IP.**
	Decision: Approved with IP specifications.	
1435.	Name and address of manufacturer/ Applicant	M/s Fozan Pharmaceutical, 36-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	Fergan Capsule 40mg
	Composition	Each capsule contains: Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy.No.4662 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	**PPI**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Losec Capsule 40mg by M/s Astra Zaneca (MHRA Approved)**
	Me-too status	**Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg. # 028239)**
	GMP status	Last GMP inspection was conducted on 25-05-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	All the data related with pellets is needed. The official monograph for the applied formulation is available in USP.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1436.	Name and address of manufacturer/ Applicant	M/s Fozan Pharmaceutical, 36-A, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	Dexlan capsule 30mg
	Composition	Each capsule contains: Dual Delayed Release Pellets of Dexlansoprazole….30mg
	Diary No. Date of R & I & fee	Dy.No.4663 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	PPI

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as delayed release capsules (while you have applied as dual delayed release)
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 25-05-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	The applied molecule is on stability. Me- too status could not be verified.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1437.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Dopark CR tablet 25/100 mg
	Composition	Each sustained- release tablet contains: Carbidopa Anhydrous Eq……25mg Levodopa……...100mg
	Diary No. Date of R & I & fee	Dy.No 4668 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Anti- parkinsons
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	Firm has submitted the following me- too which could not be verified: Sinemet extra 50/ 200mg tablet of OBS Pharma Reg. # 070446.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1438.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Dopark CR tablet 50/200 mg
	Composition	Each sustained- release tablet contains: Carbidopa Anhydrous Eq……50mg Levodopa……...200mg
	Diary No. Date of R & I & fee	Dy.No.4669 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Anti- parkinsons
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Sinemet Extra 50/200mg Tablet of M/s OBS Pakistan, Karachi 070446
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1439.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Sofair 5mg Tablet
	Composition	Each Chewable Tablet Contains:

		Montelukast as Montelukast Sodium…...……..…5mg
	Diary No. Date of R & I & fee	Dy.No.6204 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Singulair 5mg chewable of (USFDA approved)
	Me- too status	Lontuka 5mg Chewable Tablet M/s Linz Pharma 058391
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1440.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Sofair 10mg Tablet
	Composition	Each film- coated tablet contains: Montelukast as Montelukast sodium……...10mg
	Diary No. Date of R & I & fee	Dy.No.6203 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Montiget 10 mg tablets of M/s Getz Pharma (Reg.# 034838)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1441.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Retone 50mg Tablet
	Composition	Each film- coated tablet contains: Itopride HCl……...50mg
	Diary No. Date of R & I & fee	Dy.No.6202 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA Japan Approved
	Me- too status	Ganaton 50mg Tablet by M/s Abbott (Reg. # 028429)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1442.	Name and address of manufacturer/ Applicant	M/s Stallion Pharmaceuticals Pvt Ltd, 581, Sundar Industrial Estate Lahore. Contract Manufacturer M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Tygastin Dry powder for I/V Infusion 5ml
	Composition	Each vial contains: Tigecycline…….50mg
	Diary No. Date of R & I & fee	Dy.No.3507 dated 25-01-2019 Rs.50,000/- Dated 25-01-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	50mg/ vial & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Tygacil Injection 50mg by M/s Wyeth (Reg. # 045642)
	GMP status	M/s Stallion:- Not provided M/s English: - 16-01-2018 and the report concludes grant of certificate of GMP issued on 16-01-2018.
	Remarks of the Evaluator[XIII]	• No. of sections of applicant needs to be submitted. • No. of already registered drugs on contract needs to be submitted. • The official monograph for the applied drug is available in USP. • 5% overage justification. • Clarification is required either it is lyophilised cake or powder. • Section approval letter of manufacturer needs to be submitted. • GMP report of M/s Stallion Pharma needs to be submitted by the firm.
	Decision: Deferred for following: • **Number of products already approved on contract manufacturing** • **Number of approved sections with M/s Stallion Pharmaceuticals, Lahore** • **Justification of 5% overage in master formulation** • **Confirmation of required manufacturing facility with manufacturer** • **Clarification whether applied formulation is lyophilized cake or powder.**	
1443.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalzole Capsule 20mg
	Composition	Each Capsule Contains: Esomeprazole Magnesium…….20mg
	Diary No. Date of R & I & fee	Dy.No 9248 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	PPI
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as gastro resistant
	Me- too status	Esomepral 20 mg Capsules Amson Vaccines & Pharma (Pvt) Ltd, Islamabad. 043332
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	• "As esomeprazole magnesium dehydrate" is approved in MHRA. • The official monograph for the applied formulation is available in USP. • All the data related to pellets is needed and gastro resistant capsules are not applied.
	Decision: Deferred for following: • **Revision of label claim as per reference formulation.**	

	• **Data related to pellets including source of pellets, COA of pellets, GMP of pellet manufacturer and stability data of 3 batches of pellets.**	
1444.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalzole Capsule 40mg
	Composition	Each Capsule Contains: Esomeprazole Magnesium…….40mg
	Diary No. Date of R & I & fee	Dy.No.9253 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	PPI
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as gastro resistant
	Me- too status	Esomepral 40 mg Capsules Amson Vaccines & Pharma (Pvt) Ltd, Islamabad. 043333
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	As esomeprazole magnesium dihydrate is approved in MHRA. The official monograph for the applied formulation is available in USP. All the data related to pellets is needed and gastro resistant capsules are not applied.
	Decision: Deferred for following: • **Revision of label claim as per reference formulation.** • **Data related to pellets including source of pellets, COA of pellets, GMP of pellet manufacturer and stability data of 3 batches of pellets.**	
1445.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalmus Ointment 0.1% w/w
	Composition	Each gram contains: Tacrolimus……0.001gm
	Diary No. Date of R & I & fee	Dy.No 9241 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Tacrozemus Ointment of M/s Hiranis Pharma 086789
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	Tacrolimus as monohydrate is approved in MHRA. The applied formulation is non- pharmacopoeial Section needs confirmation.
	Decision: Deferred for following: • **Revision of label claim as per reference product.** • **Cofirmation of required manufacturing facility i.e., Cream / ointment section is required.**	
1446.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalmus Ointment 0.3% w/w
	Composition	Each gram contains:

		Tacrolimus…0.003gm
	Diary No. Date of R & I & fee	Dy.No.9244 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved As monohydrate and in 0.03% w/w strength
	Me- too status	Tacroderm Ointment 0.03% Caraway Pharmaceuticals, Rawat 069932
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	MHRA Approved As monohydrate and in 0.03% w/w strength The applied formulation is non- pharmacopoeial. Section needs confirmation.
	Decision: Deferred for following: • **Revision of label claim as per reference product.** • **Cofirmation of required manufacturing facility is required.**	
1447.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalgab Capsule 75mg
	Composition	Each capsule contains: Pregabalin…..…75mg
	Diary No. Date of R & I & fee	Dy.No.9248 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Pregalax Capsule of M/s Magns Pharmaceuticals, Faisalabad 084136
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	The applied formulation is non- pharmacopoeial. General capsule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
1448.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalthro Capsule 250mg
	Composition	Each capsule contains: Azithromycin Dihydrate…….250mg
	Diary No. Date of R & I & fee	Dy.No.9245 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Azithromycin 250mg Capsules of M/s Unipharma (Pvt.) Ltd., Lahore 071421

	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP. General capsule section is available in the firm as mentioned in the submitted GMP inspection report. As dihydrate is approved in reference.
	Decision: Deferred as the approved drug in reference regulatory authorities is "Azithromycin as Dihydrate" while the firm has applied "Azithromycin Dihydrate".	
1449.	Name and address of manufacturer/ Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name + Dosage Form + Strength	Kalthro Capsule 500mg
	Composition	Each capsule contains: Azithromycin dihydrate……..500mg
	Diary No. Date of R & I & fee	Dy.No.9250 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me- too status	Azithromycin 500mg Capsules of M/s Unipharma (Pvt.) Ltd., Lahore. 071422
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP. General capsule section is available in the firm as mentioned in the submitted GMP inspection report. As dihydrate will come Reference could not be confirmed.
	Decision: Deferred for following reasons: • **The approved drug in reference regulatory authorities is "Azithromycin as Dihydrate" while the firm has applied "Azithromycin Dihydrate".** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	
1450.	Name and address of manufacturer/ Applicant	M/s Caliph Pharmaceuticals Pvt Ltd, Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan.
	Brand Name + Dosage Form + Strength	Clobetacal 0.05% w/w Lotion
	Composition	Each ml lotion contains: Clobetasol Propionate……..0.05%
	Diary No. Date of R & I & fee	Dy.No.5782 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Impeklo Lotion of M/s Mylan0.05% w/w (USFDA Approved in bottle with a metered-dose pump having an integral pump locking feature)
	Me- too status	Clobeta Topical Solution of M/s Platinum Pharma Karachi 055710

	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes that the panel recommends the renewal of DML for following sections: 1- Tablet section (General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator[XIII]	• Cream/ Ointment/ Lotion section General (Antibiotic, Non-Antibiotic) is available in the firm as mentioned in the submitted section approval letter. • IMPEKLO™ lotion, 0.05% is a white to off white, opaque to translucent, homogenous and lump free lotion without any phase separation provided in a white bottle with a metered-dose pump having an integral pump locking feature. Each pump actuation delivers 0.15 mg of clobetasol propionate, USP in 0.30 g of lotion. The metered-dose pump is capable of dispensing not less than 138 actuations to deliver not less than 41.4 g of lotion. • Revise label claim as it is not clear that how to make it 0.05%. (If it is 0.5mg/ gram, then it becomes 0.05% of lotion). • Mention the container closure system. • USFDA Approved in bottle with a metered-dose pump having an integral pump locking feature • You have applied w/w while in label claim you have written each ml contains. Explain how?
	Decision: Deferred for revision of formulation as per reference product alongwith details of container closure system.	
1451.	Name and address of manufacturer/ Applicant	M/s Caliph Pharmaceuticals Pvt Ltd, Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan.
	Brand Name + Dosage Form + Strength	Erdocal Sachet 225mg
	Composition	Each sachet contains: Erdosteine……..…225mg
	Diary No. Date of R & I & fee	Dy.No.5088 dated 06-02-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved in 300mg sachet while 225mg is applied
	Me- too status	Mucolec 225 mg Sachet of M/s Wnsfeild Pharmaceutical, Industrial Estate, Hattar 078593
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes that the panel recommends the renewal of DML for following sections: 1- Tablet section (General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic)

		3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator[XIII]	• General Sachet section is available in the firm as mentioned in the submitted section approval letter. • Revise the applied strength as it is ANSM; France Approved in 300mg sachet while you have applied 225mg.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
1452.	Name and address of manufacturer/ Applicant	M/s Caliph Pharmaceuticals Pvt Ltd, Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan.
	Brand Name + Dosage Form + Strength	Vigacal 500mg Sachet
	Composition	Each sachet contains: Vigabatrin……...500mg
	Diary No. Date of R & I & fee	Dy.No.5088 dated 06-02-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Vlep 500mg Sachet of M/s Genix Pharma (Pvt.) Ltd Karachi 070474
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes that the panel recommends the renewal of DML for following sections: 1- Tablet section (General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator[XIII]	General Sachet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved.	
1453.	Name and address of manufacturer/ Applicant	M/s Caliph Pharmaceuticals Pvt Ltd, Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan.
	Brand Name + Dosage Form + Strength	Smectacal Sachet 3g
	Composition	Each sachet contains: Dioctahedral Smectite……3g
	Diary No. Date of R & I & fee	Dy.No.5090 dated 06-02-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Anti- diarrhoeal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me- too status	Semetamed 3g Sachet of M/s Mediate Pharmaceutical (Pvt.) Ltd, Karachi 061925
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes that the panel recommends the renewal of DML for following sections: 1- Tablet section (General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator[XIII]	General Sachet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved with innovators' specifications.	
1454.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Zitomax capsule 250mg
	Composition	Each capsule contains: Azithromycin as Dihydrate eq. to Azithromycin……...250mg
	Diary No. Date of R & I & fee	Dy.No.7904 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	**Macrolide antibiotic**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	**Zidor capsule 250mg of M/s Winthrox Karachi (Reg.# 074943)**
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	• **The official monograph is available in USP.** • **General capsule section is available in the firm as mentioned in the submitted GMP inspection report.**
	Decision: Approved with USP specifications.	
1455.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Somalin Syrup 100mg/ml
	Composition	Each ml of syrup contains: Citicoline as Sodium……100mg
	Diary No. Date of R & I & fee	Dy.No.7905 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Nootropics and Neutronics
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by AEMPS of Spain
	Me- too status	Cercolin Syrup of M/s Schazoo Laboratories (Reg.# 048985)

	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**General syrup section is available in the firm as mentioned in the submitted GMP inspection report.** **The applied drug is n**on- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1456.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ovatab 50mg Tablet
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R & I & fee	Dy.No 7902 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	**Ovulatory Stimulants**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Approved in MHRA**
	Me- too status	Cerophene 50mg Tab of M/s Hilton Pharma Karachi 010104
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	• **The official monograph is available in USP.**
	Decision: Approved with USP specifications.	
1457.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Migagor Syrup 0.25mg
	Composition	Each 5ml contains: Pizotifen Hydrogen Malate eq.to Pizotifen..0.25mg
	Diary No. Date of R & I & fee	Dy.No.7906 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- migraine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Sanomigran Elixir 0.25mg /5ml of M/s Phoenix, (MHRA Approved)**
	Me- too status	Pizo Syrup of M/s English Pharmaceutical Industries, Lahore 020337
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**General syrup section is available in the firm as mentioned in the submitted GMP inspection report.** **The applied drug is n**on- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1458.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Nurocobal 500mcg Tablet
	Composition	Each sugar- coated tablet contains: Mecobalamin……...500mcg
	Diary No. Date of R & I & fee	Dy.No.7903 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	**Coenzyme/ Vitamin B-12**
	Type of Form	Form- 5
	Finished product Specification	**Manufacturers**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	**PMDA Japan Approved**
	Me- too status	**Mecovit 500mcg Tablet of M/s Zumars Pharma (Pvt.) Ltd (Reg.# 057709)**
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**The official monograph for the applied formulation is available in JP.**
	Decision: Approved with JP specifications.	
1459.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noacip 125mg Suspension
	Composition	Each 5ml after reconstitution contains: Ciprofloxacin as HCl……125mg
	Diary No. Date of R & I & fee	Dy.No.5344 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Ant- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me- too status	Ciprogat of M/s Miracle Pharma 072366
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**The official monograph for the applied formulation is available in** USP. Reg. board in its 269th DRB meeting decided: Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA.
	Decision: Approved with innovators' specifications.	
1460.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noacip 250mg Suspension
	Composition	Each 5ml after reconstitution contains: Ciprofloxacin as HCl……250mg
	Diary No. Date of R & I & fee	Dy.No.5345 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Ant- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Ciprogat Miracle Pharma 072367
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**The official monograph for the applied formulation is available in** USP.

	Decision: Approved with USP specifications.	
1461.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ucon Suspension 50mg/5ml powder for oral suspension
	Composition	Each 5ml contains: Fluconazole…50mg
	Diary No. Date of R & I & fee	Dy.No.5346 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Ant- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved powder for suspension
	Me- too status	Derocon Suspension Raazee Therapeutics (Pvt) Ltd, 48KM, Lahore Kasur Road, Kasur. 027219
	GMP status	**Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.**
	Remarks of the Evaluator[XIII]	**The official monograph for the applied formulation is available in** USP.
	Decision: Approved with USP specifications.	
1462.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wenorol 10mg tablet
	Composition	Each uncoated tablet contains: Bambuterol HCl……..…….10mg
	Diary No. Date of R & I & fee	Dy.No.41358 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Long acting beta adreno receptor agonist (drugs for obstructive airway disease)
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me- too status	Bambuzaf tablet of M/s Zafa Pharma 067573
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1463.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wentowin 10mg capsule
	Composition	Each capsule contains: Acitretin…..…..10mg
	Diary No. Date of R & I & fee	Dy.No.41356 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psoriatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	ACT 10mg Capsule Ciba Pharma 081575
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator[XIII]	General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1464.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wentowin 25mg capsule
	Composition	Each capsule contains: Acitretin…….25mg
	Diary No. Date of R & I & fee	Dy.No.41370 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psoriatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Acitec 25 mg Capsules Panacea Pharma 069843
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1465.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wefex 50mg XR Tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Desvenlafaxine Succinate Eq. to Desvenlafaxine…50mg
	Diary No. Date of R & I & fee	Dy.No.41380 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Desven XR 50mg Tablet Pharmevo Kar 080283
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1466.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wefex 100mg XR Tablet
	Composition	Each extended - release film- coated tablet contains: Desvenlafaxine Succinate eq. to Desvenlafaxine.100mg
	Diary No. Date of R & I & fee	Dy.No.41381 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	innovators
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Desvel XR 100mg tablet of M/s Hilton Pharma 070760
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1467.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wastin 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin Calcium Eq. to Pitavastatin…1mg
	Diary No. Date of R & I & fee	Dy.No.41377 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	HMG Co- A reductase Inhibitor
	Type of Form	Form- 5
	Finished product Specification	JP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Pitastin 1mg Tablet Atco Lab 081095
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1468.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wastin 2mg Tablet
	Composition	Each film- coated tablet contains: Pitavastatin Calcium Eq. to Pitavastatin…….2mg
	Diary No. Date of R & I & fee	Dy.No.41376 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	HMG Co- A Reductase Inhibitor
	Type of Form	Form- 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Pitastin 2mg tablet of M/s Atco Lab 081094
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1469.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals., Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wastin 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin Calcium Eq. to Pitavastatin…4mg
	Diary No. Date of R & I & fee	Dy.No.41375 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	HMG Co- A reductase Inhibitor
	Type of Form	Form- 5
	Finished product Specification	JP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Pitastin 4mg Tablet Atco Lab 081093
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.

	Decision: Approved.	
1470.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wemride 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R & I & fee	Dy.No 41382 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me- too status	Solium-50 Tablets of Genomen Pharma 064017
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML. The official monograph for the applied formulation is available in BP while USP monograph is applied.
	Decision: Approved.	
1471.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wemride 100mg tablet
	Composition	Each tablet contains: Amisulpride……100mg
	Diary No. Date of R & I & fee	Dy.No 41383 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me- too status	Ampisol 100mg Tablet of M/s Sami Karachi 076061
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML. The official monograph for the applied formulation is available in BP while USP monograph is applied.
	Decision: Approved with BP specifications.	
1472.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wemride 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…200mg
	Diary No. Date of R & I & fee	Dy.No 41384 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me- too status	Ampisol 100mg Tablet of M/s Sami Karachi 076061
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML. The official monograph for the applied formulation is available in BP while USP monograph is applied.
	Decision: Approved with BP specifications.	
1473.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Busowen 5mg Tablet
	Composition	Each uncoated tablet contains: Buspirone HCl……..…...5mg
	Diary No. Date of R & I & fee	Dy.No.41379 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anxiolytic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Buspro Tablet 5mg of M/s Saydon Pharma 080227
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1474.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Busowen 10mg Tablet
	Composition	Each uncoated tablet contains: Buspirone HCl……..…...10mg
	Diary No. Date of R & I & fee	Dy.No.41378 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anxiolytic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Buspro Tablet 5 mg Saydon Pharma080227
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1475.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wezovast 10/10 mg Tablet
	Composition	Each film coated tablet contains: Ezetimibe…….10mg Atorvastatin Calcium Eq. to Atorvastatin…10mg
	Diary No. Date of R & I & fee	Dy.No.41386 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Atorax-E Tablets of M/s Dyson Research Laboratories 078838

	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1476.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name + Dosage Form + Strength	Wezovast 10/20 mg Tablet
	Composition	Each film- coated tablet contains: Ezetimibe……10mg Atorvastatin Calcium Eq. to Atorvastatin…20mg
	Diary No. Date of R & I & fee	Dy.No.41387 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Lipiget EZ 20mg+10mg Tablet of Getz Pharma 073714
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1477.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Welpinde 5/40 mg Tablet
	Composition	Each bi-layered uncoated tablet contains: Amlodipine Besylate Eq. to Amlodipine……5mg Telmisartan……40mg
	Diary No. Date of R & I & fee	Dy.No.41363 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Telam 5mg/ 40 mg tablet of M/s Macter International, Kar (Reg. # 079540)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • **Evidence of required manufacturing equipment i.e. tablet bi-layered machine and Reports of submission of Installation Qualification & Performance Qualification Reports of tablet bi-layered machine.**
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.	
1478.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Welpinde 5/80 mg Tablet
	Composition	Each Bi-Layered Uncoated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…5mg Telmisartan…80mg

	Diary No. Date of R & I & fee	Dy.No 41365 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Telam 5mg/ 80 mg tablet of M/s Macter International, Karachi (Reg. # 079541)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • **Evidence of required manufacturing equipment i.e. tablet bi-layered machine and Reports of submission of Installation Qualification & Performance Qualification Reports of tablet bi-layered machine.**
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.	
1479.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Welpinde 40/10mg Tablet
	Composition	Each bi-layered uncoated tablet contains: Amlodipine Besylate Eq. to Amlodipine……..10mg Telmisartan……40mg
	Diary No. Date of R & I & fee	Dy.No.41364 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Amtas 10mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 066945)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • **Evidence of required manufacturing equipment i.e. tablet bi-layered machine and Reports of submission of Installation Qualification & Performance Qualification Reports of tablet bi-layered machine.**
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.	
1480.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Welpinde 10/80 mg Tablet
	Composition	Each Bi-Layered Uncoated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…10mg Telmisartan…80mg
	Diary No. Date of R & I & fee	Dy.No 41366 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5

	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me- too status	Misar-Am 80/10mg Tablet of M/s Highnoon Pharma (Pvt) Ltd (Reg. # 069151)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The official monograph for the applied formulation is available in USP. • **Evidence of required manufacturing equipment i.e. tablet bi-layered machine and Reports of submission of Installation Qualification & Performance Qualification Reports of tablet bi-layered machine.**
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.	
1481.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wolme 5/20 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine……5mg Olmesartan Medoxomil……..…20mg
	Diary No. Date of R & I & fee	Dy.No 41389 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Baritec-A 20/5mg Tablet Barrett Hodgson 081442
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved.	
1482.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wolme 5/40 mg Tablet
	Composition	Each film- coated tablet contains: Amlodipine Besylate Eq. to Amlodipine……..…5mg Olmesartan Medoxomil……..…40mg
	Diary No. Date of R & I & fee	Dy.No.41360 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Baritec-A 40/5mg Tablet Barrett Hodgson 081443
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML.

		• The applied formulation is non- pharmacopoeial.
	Decision: Approved.	
1483.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wolme Tablet 10/ 20mg
	Composition	Each film- coated tablet contains: Amlodipine Besylate Eq. to Amlodipine…….10mg Olmesartan Medoxomil……20mg
	Diary No. Date of R & I & fee	Dy.No 41390 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me- too status	Baritec-A 20/10mg Tablet Barrett Hodgson 081444
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved.	
1484.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wentowen 24mg tablet
	Composition	Each uncoated tablet contains: Betahistine Dihydrochloride…….24mg
	Diary No. Date of R & I & fee	Dy.No.41369 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me- too status	Enier 24mg Tablet Sami Pharma 076757
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1485.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wentowen 48mg Tablet
	Composition	Each Uncoated Tablet Contains: Betahistine Dihydrochloride…48mg
	Diary No. Date of R & I & fee	Dy.No 41385 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in the applied strength as available strengths are 8mg, 16mg and 24mg
	Me- too status	Statobex 48mg Tablet of M/s Atco Laboratories Limited 058433
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • International availability could not be confirmed in the applied strength as available strengths are 8mg, 16mg and 24mg.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1486.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wenotin 500mg Tablet
	Composition	Each film -coated tablet contains: Vigabatrin…….……500mg
	Diary No. Date of R & I & fee	Dy.No.41368 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Seizril 500mg Tablet of M/s Nabiqasim Kar 081564
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1487.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Wenzer 250mg capsule
	Composition	Each capsule contains: Cycloserine…..250mg
	Diary No. Date of R & I & fee	Dy.No.41371 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Cyclosen Capsules of M/s Schazoo Laboratories 035272
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Deferred for applied pharmacological group as the applied drug is an Antibiotic and not an anti- epileptic.	
1488.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name + Dosage Form + Strength	Maxin 50mg Tablet
	Composition	Each film coated tablet contains: Naltrexone HCl…….50mg
	Diary No. Date of R & I & fee	Dy.No.41361 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Opioid Antagonist (Drugs used in addictive disorders)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	E-Track 50mg Tablet of M/s Elko 070791
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1489.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Wespone 50mg Tablet
	Composition	Each sugar coated tablet contains: Eperisone Hydrochloride…….50mg
	Diary No. Date of R & I & fee	Dy.No.41359 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Myonal 50mg tablets (PMDA; Japan Approved)
	Me- too status	Peson Tablet 50mg of M/s Regal Pharma 081955
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved.	
1490.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Woxim 20mg Tablet
	Composition	Each film coated tablet contains: Tenoxicam…..……20mg
	Diary No. Date of R & I & fee	Dy.No.41367 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Tenoxicam Tablets of M/s Alina Combine 020529
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is available in BP while the firm has applied USP.
	Decision: Approved.	
1491.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Febux tablet 120mg
	Composition	Each film- coated tablet contains: Febuxostat Dihydrochloride...……...……120mg
	Diary No. Date of R & I & fee	Dy.No.41357 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Febustat Tablet of M/s Wimits Pharma 086278
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial. • Initially, in applied master formulation Tfebuxzidine Dihydrochloride was mentioned while in Form- 5 Febuxostat was written. On fee-challan only brand name is mentioned. • Now, the firm has revised its Form- 5 and master formulation as Febuxostat and has submitted 20,000 fees for new application.
	Decision: Approved with innovators' specifications.	
1492.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Wemarox 85/500 mg Tablet
	Composition	Each uncoated tablet contains: Sumatriptan Succinate Eq. to Sumatriptan……...85mg Naproxen Sodium……500mg
	Diary No. Date of R & I & fee	Dy.No.41362 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Selective 5 HT1 receptor agonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA; Australia as film- coated
	Me- too status	Imtaxen Tablet of M/s Shaigan Pharma 081678
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • Initiallly, it was applied as uncoated while is approved in TGA; Australia as film- coated. • Firm has revised the formulation according to the reference and has submitted the requisite fees for revision of formulation as Rs. 5000/- under deposit slip # 2045302 dated 10-07-2020. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1493.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Wencolin 100mg Tablet
	Composition	Each film- coated tablet contains: Minocycline Hydrochloride eq. to Minocyclin...100mg
	Diary No. Date of R & I & fee	Dy.No.41382 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Tetracycline Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me- too status	Minoderm tablets of M/s Martin Dow Pharma 024308

	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • Initially, on Form- 5, 100mg was written and on fee-challan 500mg was mentioned. While in composition 400mg was applied. • Firm has revised the strength from 500mg to 100mg and has deposited Rs. 20,000/- fees under deposit slip # 2045304 dated: 10-07-2020.
	Decision: Deferred for the applied strength as initially, on Form- 5, 100mg was written and on fee-challan 500mg was mentioned. While in composition 400mg was applied.	
1494.	Name and address of manufacturer/ Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Brand Name + Dosage Form + Strength	Wetrole Capsule 100mg
	Composition	Each capsule contains: Itraconazole as IR Pellets ……..100mg
	Diary No. Date of R & I & fee	Dy.No.41372 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me- too status	Zitracon Capsules 100mg of M/s Meditech Pharma 073346
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• General capsule section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1495.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma, Plot No 2610. Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Esglit tablet 5mg
	Composition	Each film- coated tablet contains: Escitalopram Oxalate Eq. to Escitalopram….....5mg
	Diary No. Date of R & I & fee	Dy.No.2090 dated 16-01-2019 Rs.20,000/- Dated 17-01-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 50's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Rize- plus tablet 5 mg of M/s Werrick Pharmaceuticals Islamabad (Reg.# 068875)
	GMP status	The firm was inspected on 16.01.2019. The panel recommended the grant of GMP certificate.
	Remarks of the Evaluator[XIII]	• Methylene chloride has been used in the applied coating solution. • Firm has general tablet section as mentioned in the submitted GMP inspection report.
	Decision: Deferred as a banned excipient Methylene chloride has been used in the applied coating solution.	
1496.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Diabex tablet1000mg

	Composition	Each film coated tablet contains: Metformin HCl…….1000mg
	Diary No. Date of R & I & fee	Dy.No.3954 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	1. ANSM; France Approved
	Me- too status	Glucophage Tablets 1Gm Merck Marker (Pvt.) Ltd, 7-Jail Road, Quetta 025488
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator[XIII]	The official monograph for the applied product is available in USP.
	Decision: Approved with USP specifications.	
1497.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Itrosac Capsules 100mg
	Composition	Each capsule contains: Itraconazole……...…100mg
	Diary No. Date of R & I & fee	Dy.No.3951 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti-fungal
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	4's, 10's, 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Mukil Capsule 100mg of M/s. Dyson Research Laboratories (Pvt.) Ltd (Reg.# 055356)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator[XIII]	Source of pellets is M/s Vision Pharmaceuticals, Kahuta Road, Islamabad and data related to pellets is submitted.
	Decision: Approved.	
1498.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot# 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Irbest 150mg tablet
	Composition	Each film coated tablet contains: Irbesartan……..…150mg
	Diary No. Date of R & I & fee	Dy.No.756 dated 07-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved

	Me- too status	Arbi 150mg Tablet of M/s Pharm Evo (Reg.# 073769)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Tablet general section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1499.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot# 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Irbest 300mg Tablet
	Composition	Each film coated tablet contains: Irbesartan…….300mg
	Diary No. Date of R & I & fee	Dy.No.757 dated 07-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Irecon 300mg tablet of M/s Barrett Hodgson (Reg.# 039727)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Tablet general section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1500.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt) Ltd, Plot# 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Irbest-H Tablet150/12.5 mg
	Composition	Each film coated tablet contains: Irbesartan…….150mg Hydrochlorothiazide…...12.5mg
	Diary No. Date of R & I & fee	Dy.No.758 dated 07-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Anti- hypertensive/ Diuretic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Irbest Plus tablet of M/s Highnoon (Reg. # 077110)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Tablet general section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1501.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt) Ltd, Plot# 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Irbest-H Tablet300/12.5 mg
	Composition	Each film coated tablet contains: Irbesartan…….300mg Hydrochlorothiazide…..12.5mg
	Diary No. Date of R & I & fee	Dy.No.759 dated 07-01-2019 Rs.20,000/- Dated 04-01-2019

	Pharmacological Group	Anti- hypertensive/ Diuretic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Irbest Plus Tabletsof M/s Highnoon Laboratories, Lahore 077111
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Tablet general section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1502.	Name and address of manufacturer/ Applicant	M/s Horizon Healthcare (Pvt) Ltd, Plot# 33, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Lewdes 0.5mg Oral Syrup
	Composition	Each ml contains: Desloratadine……0.5mg
	Diary No. Date of R & I & fee	Dy.No.755 dated 07-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Anti- hypertensive/ Diuretic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	60ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	Aerius for Children Syrup desloratadine 2.5mg/5ml oral liquid TGA; Australia Approved
	Me- too status	Mdisin 2.5mg Syrup M/s Metro Pharmaceuticals, Islamabad081671
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	• Oral liquid general section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1503.	Name and address of manufacturer/ Applicant	M/s Karachi Pharmaceutical Laboratories, S/ 54, Mauripur Road, SITE, Karachi.
	Brand Name + Dosage Form + Strength	Calm tablet 1mg
	Composition	Each tablet contains: Alprazolam…..1mg
	Diary No. Date of R & I & fee	Dy.No.1671 dated 14-01-2019 Rs.20,000/- Dated 09-01-2019
	Pharmacological Group	Anxiolytic agent Antidepressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Xanax 1mg by M/s Pharmacia and UpJohns, USFDA Approved
	Me- too status	Lydia 1mg Tablet of M/s. Wilshire LabReg. 065699
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	• GMP report is not submitted. • Section needs to be verified. • The official monograph is available in USP.
	Decision: Deferred for following reasons: • **Confirmation of required manufacturing facility /section from Licensing Division.**	

	• **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1504.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Emapaglif- M tablet12.5/500mg
	Composition	Each film coated tablet contains: Empagliflozin……..…..…12.5mg Metformin HCl……500mg
	Diary No. Date of R & I & fee	Dy.No.9022 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Deferred for submission of stability data as per requirement determined in 293rd meeting of Registration Board.	
1505.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Birone tablet 5mg
	Composition	Each tablet contains: Buspirone HCl ……..……5mg
	Diary No. Date of R & I & fee	Dy.No.7420 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Benzodiazepines (Anxiolytic)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Busron 5mg Tablets of M/s SJ & G Fazul Ellahie (Pvt.) Ltd, Karachi 020564
	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1506.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Zefigesic 200mg Tablet
	Composition	Each film-coated oral tablet contains: Dexibuprofen…….……200mg
	Diary No. Date of R & I & fee	Dy.No.7419 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me- too status	Dofen 200mg Tablet of Maple Pharmaceuticals Karachi 061139

	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1507.	Name and address of manufacturer/ Applicant	M/s Epla Laboratories, D-12, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	Myconit-V Cream
	Composition	Each gm contains: Miconazole Nitrate……20mg
	Diary No. Date of R & I & fee	Dy.No.5899 dated 11-02-2019, Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Gynostin Cream of M/s Bloom Pharmaceuticals Hattar 025468
	GMP status	Last GMP inspection was conducted on 11-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in BP. • General Ointment/ Cream section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Deferred for confirmation of already of registered formulation for M/s Epla Laboratories, Karachi.	
1508.	Name and address of manufacturer/ Applicant	M/s Epla Laboratories, D-12, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	Myconit Clin-V Cream
	Composition	Each gram cream contains: Clindamycin Phosphate……20mg
	Diary No. Date of R & I & fee	Dy.No.5901 dated 11-02-2019, Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Clindanor 2 % Cream of M/s Nortech Pharma Islamabad 077982
	GMP status	Last GMP inspection was conducted on 11-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in USP. • General Ointment/ Cream section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Deferred for confirmation of already of registered formulation for M/s Epla Laboratories, Karachi.	
1509.	Name and address of manufacturer/ Applicant	M/s Epla Laboratories, D-12, Estate Avenue, S.I.T.E., Karachi.
	Brand Name + Dosage Form + Strength	Myconit Oral Gel
	Composition	Each gram contains: Miconazole……...20mg
	Diary No. Date of R & I & fee	Dy.No.5900 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Miconal 2% Gel of M/s Ciba Pharmaceuticals, Karachi 081513
	GMP status	Last GMP inspection was conducted on 11-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[XIII]	• The official monograph for the applied formulation is available in BP. • General Ointment/ Cream section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Deferred for confirmation of already of registered formulation for M/s Epla Laboratories, Karachi.	
1510.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Cynova 10mg Tablet
	Composition	Each film coated tablet contains: Leflunomide…..……...…10mg
	Diary No. Date of R & I & fee	Dy.No.7418 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Selective Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Lefonate tablets 10mg of M/s Fassgen Pharmaceuticals (Reg. # 070350)
	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1511.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Urifix 5mg Tablets
	Composition	Each film coated tablet contains: Solifenacin succinate……5mg
	Diary No. Date of R & I & fee	Dy.No.7415 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Anti- spasmodic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Solifen 5mg Tablet of Getz Pharma Karachi 061202
	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
1512.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Urifix 10mg Tablets
	Composition	Each film coated tablet contains: Solifenacin succinate…….10mg

	Diary No. Date of R & I & fee	Dy.No.7416 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Muscarinic antagonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Solifen Tablet 10mg of M/s Getz Pharma 061203
	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	Non- phramacopoeial.
	Decision: Approved with innovators' specifications.	
1513.	Name and address of manufacturer/ Applicant	M/s Zephyr Pharmatec Pvt. Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Agotin 25mg Tablet
	Composition	Each film- coated tablet contains: Agomelatine……25mg
	Diary No. Date of R & I & fee	Dy.No.7417 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	7's, 10's, 14's, 28's& as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA, Australia Approved
	Me- too status	Valdoxan tablet 25mg of M/s Servier (Reg. # 078160)
	GMP status	Last GMP inspection was conducted on 30-01-2018 and the report concludes that the GMP compliance of the firm is rated as good.
	Remarks of the Evaluator[XIII]	Non- phramacopoeial.
	Decision: Approved with innovators' specifications.	
1514.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Globigen 100mg chewable tablet
	Composition	Each chewable tablet contains: Iron- III Hydroxide Polymaltose Complex eq. to elemental iron……100mg
	Diary No. Date of R & I & fee	Dy.No.8686 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- Anaemic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me- too status	Misleri Tablets 100 mg of Ambrosia Pharma Industrial Zone, Rawat 069974
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
1515.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Neolepra 5mg Tablet
	Composition	Each film coated tablet contains: Olanzapine……5mg

	Diary No. Date of R & I & fee	Dy.No.8684 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 28's& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Olanzapine-Sandoz 5mg Tablets of M/s Novartis Pharma, Karachi. (Reg. # 064040)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1516.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Neolepra 7.5mg Tablet
	Composition	Each film coated tablet contains: Olanzapine……7.5mg
	Diary No. Date of R & I & fee	Dy.No.8683 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 28's& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Olzar of Bryon 068323
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1517.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name + Dosage Form + Strength	Neolepra 10mg Tablet
	Composition	Each film coated tablet contains: Olanzapine……10mg
	Diary No. Date of R & I & fee	Dy.No.8685 dated 27-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 28's& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me- too status	Olanzpine 10 mg Tablets of M/s Akson Pharmaceuticals Pvt Ltd. Mirpur (Reg.#081661)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator[XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
1518.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unimate 200mg Tablet
	Composition	Each film- coated tablet contains: Topiramate……200mg
	Diary No. Date of R & I & fee	Dy.No.17213 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019

	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	6x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Topirax Tablets 200mg of M/sFeroza International Pharma (Pvt.) Ltd, Lahore 041657
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1519.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Tec- cedol Tablet 325/37.5mg
	Composition	Each film-coated tablet contains: Paracetamol…….325mg Tramadol HCl……..…37.5mg
	Diary No. Date of R & I & fee	Dy.No.17209 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Tramadoln Plus Tablet 37.5+325mg of M/s Akson Pharma Azad Kashmir 085459
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	TGA; Australia Approved as film-coated The official monograph for the applied formulation is available in USP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1520.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Lamotech 50mg Tablet
	Composition	Each film- coated tablet contains: Lacosamide……50mg
	Diary No. Date of R & I & fee	Dy.No.17243 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Lacosbar 50mg Tablet of Barrett Hodgson Kar 083224

	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21stMay, 2019. • Section needs to be confirmed. • Non- pharmacopoeial.
	Decision: Deferred for consideration on its turn.	
1521.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Lamotech 100mg Tablet
	Composition	Each film- coated tablet contains: Lacosamide……..…100mg
	Diary No. Date of R & I & fee	Dy.No.17234 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Lacosbar 100mg Tablet of Barrett Hodgson Kar 083223
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • Non- pharmacopoeial.
	Decision: Deferred for consideration on its turn.	
1522.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unizapine Tablet 30mg
	Composition	Each film- coated tablet contains: Mirtazapine…….30mg
	Diary No. Date of R & I & fee	Dy.No.17235 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Mirtazep Tablets of M/s Zafa Pharmaceuticals Laboratories Industrial Area Karachi 024216
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• The official monograph is available in BP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1523.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unizapine 45mg Tablet
	Composition	Each film- coated tablet contains: Mirtazipine……..45mg
	Diary No. Date of R & I & fee	Dy.No.17242 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019

	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Remeron Tablets 45mg of M/s Organon Pakistan Karachi 026398
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	The official monograph is available in BP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1524.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Uninox 200mg/5ml DS Suspension
	Composition	Each 5ml contains: Cefixime trihydrate ……..……..200mg
	Diary No. Date of R & I & fee	Dy.No.17214 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Megnett DS Oral Suspension of S.J. & G Fazul Ellahie (Pvt.) Ltd, E-46, SITE, Karachi 024000
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• The official monograph is available in USP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • As trihydrate will come
	Decision: Deferred for consideration on its turn.	
1525.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Ulanza Tablet 5mg
	Composition	Each film-coated tablet contains: Olanzapine……...…5mg
	Diary No. Date of R & I & fee	Dy.No.17245 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Olanzapine- Sandoz 5mg Tablets of M/s Novartis Pharma, Karachi 048411
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	The official monograph is available in BP.

		• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1526.	Name and address of manufacturer/ Applicant	M/s Uni- Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Ulanza 10mg Tablet
	Composition	Each film-coated tablet contains: Olanzapine…….10mg
	Diary No. Date of R & I & fee	Dy.No.17210 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Olanzapine- Sandoz 10mg Tablets of M/s Novartis Pharma, Karachi 048412
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	The official monograph is available in BP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1527.	Name and address of manufacturer/ Applicant	M/s Unitiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unitropide 150mg Capsule
	Composition	Each capsule contains: Itopride HCl SR pellets……...…150mg
	Diary No. Date of R & I & fee	Dy.No.17233 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • Non- pharmacopoeial. • Reference and me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1528.	Name and address of manufacturer/ Applicant	M/s Unitiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Lumisuag 40/240mg Tablet
	Composition	Each tablet contains: Artemether……40mg Lumefantrine……..240mg
	Diary No. Date of R & I & fee	Dy.No.17237 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- malarial

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	8's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation as uncoated tablet
	Me-too status	Artemef Fort Tablet 40/240mg of M/s Panacea Pharmaceuticals Rawat, Islamabad 056334
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • Coating process is mentioned in the manufacturing outline but not in master formulation. • Product is in International pharmacopoeia.
	Decision: Deferred for consideration on its turn.	
1529.	Name and address of manufacturer/ Applicant	M/s Unitiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Sardipine Tablet 5/80mg
	Composition	Each film- coated tablet contains: Amlodipine Besylate …….5mg Valsartan……...80mg
	Diary No. Date of R & I & fee	Dy.No.17228 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Angiotensin-II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amlodine Tablet 5/80 of M/s Jupiter Pharma, Rawat Islamabad 081931
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• As besylate would come • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1530.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Sardipine 10/160mg Tablet
	Composition	Each film- coated tablet contains: Amlodipine…10mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy.No 17227 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Angiotensin II receptor blocker/ Calcium channel blocker
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amlodine Tablet 10/ 160 of M/s Jupiter Pharma Plot # 25, St# S6 RCCI, Rawat Islamabad 081933

	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1531.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Respiritech 3mg Tablet
	Composition	Each film- coated tablet contains: Risperidone……..3mg
	Diary No. Date of R & I & fee	Dy.No.17223 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Risperin Tablet of M/s Hansel Pharmaceuticals, Lahore 041348
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	The official monograph is available in USP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1532.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Respiritech 4mg Tablet
	Composition	Each film- coated tablet contains: Risperidone……..4mg
	Diary No. Date of R & I & fee	Dy.No.17231 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Risperidone- Sandoz 4mg Tablet of M/s Novartis Pharma, Karachi Pakistan 048834
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	The official monograph is available in USP. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1533.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Dicflake 100mg SR Tablet

	Composition	Each film- coated SR tablet contains: Diclofenac Sodium……100mg
	Diary No. Date of R & I & fee	Dy.No.17246 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Konac SR Tablets of M/s Remington Pharmaceutical Industries, Lahore 020535
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1534.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Alfatech 0.5mcg Tablet
	Composition	Each tablet contains: Alfacalcidol……...0.5mcg
	Diary No. Date of R & I & fee	Dy.No.17247 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Vitamin D and Analogue
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA; Japan Approved
	Me-too status	Alfacal Tablet of M/s Platinum Pharmaceuticals (Pvt.) Ltd, Karachi 026683
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • Coating process is mentioned in the manufacturing outline but not in master formulation. While the applied tablet is uncoated in reference and in Form- 5 it is written correct.
	Decision: Deferred for consideration on its turn.	
1535.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Drotech Injection 40mg/2ml
	Composition	Each 2ml contains: Drotaverine HCl……40mg
	Diary No. Date of R & I & fee	Dy.No.17207 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	**Anesthetic**
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 25's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	NO- SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) & NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved)

	Me-too status	**Spastop 40mg/2ml of City Pharma, Karachi** 075840
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1536.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Acetech Tablet 100mg
	Composition	Each film- coated tablet contains: Aceclofenac……..100mg
	Diary No. Date of R & I & fee	Dy.No.17230 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Aceclo Tablet of M/s Allied Medical Supplies (Pvt.) Ltd. Karachi 061822
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1537.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Esitech 20mg Tablet
	Composition	Each film- coated tablet contains: Escitalopram Oxalate…….....20mg
	Diary No. Date of R & I & fee	Dy.No.17241 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	SSRIs/ Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Safepram of Martin Dow
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • Escitalopram as Oxalate is approved in MHRA.
	Decision: Deferred for consideration on its turn.	
1538.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unimotrigine 5mg Tablet
	Composition	Each film- coated tablet contains: Lamotrigine……..5mg
	Diary No. Date of R & I & fee	Dy.No 17232 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019

	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as chewable tablet
	Me-too status	Lamictal of M/s GSK
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • USFDA Approved as chewable tablet.
	Decision: Deferred for consideration on its turn.	
1539.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unimotrigine 200mg Tablet
	Composition	Each film- coated tablet contains: Lamotrigine……200mg
	Diary No. Date of R & I & fee	Dy.No.17236 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as orally disintegrating tablets
	Me-too status	Could not be confirmed in the applied strength
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • The official monograph for the applied formulation is available in BP. • USFDA Approved as orally disintegrating tablets • Me- too status could not be confirmed in the applied strength.
	Decision: Deferred for consideration on its turn.	
1540.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Uniyetine 25mg CR Tablet
	Composition	Each enteric, film-coated & controlled- release tablet contains: Paroxetine……25mg
	Diary No. Date of R & I & fee	Dy.No.17224 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- depressant/ SSRI
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Paroxin CR Tablets of M/s Shrooq Pharmaceuticals (Pvt) Ltd, Lahore 060470

	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1541.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unitram 100mg Capsule
	Composition	Each SR capsule contains: Tramadol HCl…...100mg
	Diary No. Date of R & I & fee	Dy.No.17226 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zultra SR 100mg M/s Wilshire Laboratories (Pvt.) Ltd; Lahore 080714
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Source of pellets and all the data related to pellets is needed. • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1542.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Unitram Injection 100mg/2ml
	Composition	Each 2ml contains: Tramadol……100mg
	Diary No. Date of R & I & fee	Dy.No.17215 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2mlx 5's &As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as Ampoule
	Me-too status	Trauma-Nil 100mg Injection of M/s Global Pharmaceuticals, Industrial Area, Islamabad 026987
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • HCl is approved in reference. • Ampoule or vial.
	Decision: Deferred for consideration on its turn.	

1543.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Uni Cyan 500mcg/ml Injection
	Composition	Each ml contains: Cyanocobalamin…….500mcg
	Diary No. Date of R & I & fee	Dy.No.17229 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Vitamin B-12
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in the applied strength (1mg/ ml is available in USFDA while applied one is 0.5mg/ml)
	Me-too status	Cyanocobalamin Inj of M/s Multi Pharma Lahore 013207
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. **According to DRB meeting 292nd:** **Clarification is required from Licensing Division regarding approval of required manufacturing facility & manufacturing equipment for applied drug product.** **Clarification is required from firm regarding method used for sterilization of applied drug product.** **Reference could not be confirmed in the applied strength.**
	Decision: Deferred for consideration on its turn.	
1544.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Uni Cyan 1000mcg/2ml Injection
	Composition	Each 2ml contains: Cyanocobalamin…….1000mcg
	Diary No. Date of R & I & fee	Dy.No.17208 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Vitamin B-12
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in the applied strength (1mg/ ml is available in USFDA while applied one is 0.5mg/ml)
	Me-too status	Cyanocobalamin Inj of M/s Multi Pharma Lahore 013207
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. **According to DRB meeting 292nd:** **Clarification is required from Licensing Division regarding approval of required manufacturing facility & manufacturing equipment for applied drug product.** **Clarification is required from firm regarding method used for sterilization of applied drug product.** **Reference could not be confirmed in the applied strength.**
	Decision: Deferred for consideration on its turn.	
1545.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Cipflke 125mg/ml Suspension

	Composition	Each 5ml contains: Ciprofloxacin as lactate……..125mg
	Diary No. Date of R & I & fee	Dy.No.17225 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Not available as 125mg/5ml suspension but already approved by Registration Board based on domestic needs, dosage for children and its stated quantitative composition in SmPC.**
	Me-too status	**Hiflox 125mg/5ml Dry Suspension of Hilton Pharma (Reg. # 067498)**
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• **Source of granules needs to be submitted.** • Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed. • DRB in its 290th meeting a**pproved the case with innovators' specifications. With the condition that diluent shall be as per innovators' composition.**
	Decision: Deferred for consideration on its turn.	
1546.	Name and address of manufacturer/ Applicant	M/s Uni Tiech Pharmaceuticals, Plot # 4/116, Sec- 21, Korangi Industrial Area Karachi.
	Brand Name + Dosage Form + Strength	Cipflke 250mg/ml Suspension
	Composition	Each 5ml contains: Ciprofloxacin as lactate……..250mg
	Diary No. Date of R & I & fee	Dy.No.17244 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ciprofoz Dry Suspension 250mg of M/s Fozan Pharmaceuticals Industries (Pvt.)Ltd, Hayatabad, Peshawar 064463
	GMP status	Last GMP inspection was conducted on 21-05-2019 and the report concludes show-cause Notice/ Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator[XIII]	• Production of the firm is suspended from 21st May, 2019. • Section needs to be confirmed.
	Decision: Deferred for consideration on its turn.	
1547.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Linamethyst Tablet
	Composition	Each Film Coated Tablet Contains: Linagliptin…….2.5mg Metformin HCl…….500mg
	Diary No. Date of R & I & fee	Dy.No.16477 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	Manufactures

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1548.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Linajenta 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Linagliptin……5mg
	Diary No. Date of R & I & fee	Dy.No.16474 dated 07-03-2019 Rs.20,000/- Dated 06-03 -2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM; France Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1549.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Vortex 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide..10mg
	Diary No. Date of R & I & fee	Dy.No.16317 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1550.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Cilinem 500/500 mg Injection
	Composition	Each Vial Contains: Imipenem Monohydrate……..…500mg Cilastatin Sodium…….500mg
	Diary No. Date of R & I & fee	Dy.No.16320 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	Manufactures

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stanem Injection 500mg of M/s Cirin Pham. (Pvt.) Ltd., Hattar 069743
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP. I/M or I/V? Applied volume?
	Decision: Deferred for consideration on its turn.	
1551.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Ertamark 1g Dry Injection I/V
	Composition	Each Vial Contains: Ertapenem……..1g
	Diary No. Date of R & I & fee	Dy.No.16316 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as lyophilized powder
	Me-too status	Invanz Injection 1g of M/s Muller & Phipps Pakistan (Pvt.) Ltd., Karachi 043051
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. USFDA Approved as lyophilized powder
	Decision: Deferred for consideration on its turn.	
1552.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Meromark 500mg Dry Injection I/V
	Composition	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem……500mg
	Diary No. Date of R & I & fee	Dy.No.16321 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Merem of M/s Global Pharmaceuticals 038073
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1553.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Calcet 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Cinacalcet HCl……...60mg
	Diary No. Date of R & I & fee	Dy.No.16471 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti- parathyroid agent
	Type of Form	Form-5

	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1554.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Aziltan 20mg Tablet
	Composition	Each Tablet Contains: Azilisartan Medoxomil as Potassium……...20mg
	Diary No. Date of R & I & fee	Dy.No.16468 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Angiotensin- II Receptor blocker
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1555.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Alup 12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Alogliptin Benzoate……12.5mg
	Diary No. Date of R & I & fee	Dy.No.16466 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed
	Decision: Deferred for consideration on its turn.	
1556.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Diazep 10mg Tablet
	Composition	Each Tablet Contains: Diazepam……..10mg
	Diary No. Date of R & I & fee	Dy.No.16315 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diazepam 10mg Tab of M/s Star Labs Lahore 005619
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for consideration on its turn.	
1557.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Cilinem 250/250 mg Injection
	Composition	Each Vial Contains: Imipenem Monohydrate…250mg Cilastatin Sodium…250mg
	Diary No. Date of R & I & fee	Dy.No 16319 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Cilapen 250mg Injections of M/s Bosch Pharmaceuticals, 048490
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP. I/M or I/V? Applied volume?
	Decision: Deferred for consideration on its turn.	
1558.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Clon 2mg Tablet
	Composition	Each Tablet Contains: Clonazepam…...2mg
	Diary No. Date of R & I & fee	Dy.No.16314 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Clonatril Tablet of M/s Polyfine Chempharma, Peshawar 024098
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for consideration on its turn.	
1559.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Alap 0.5mg Tablet
	Composition	Each Tablet Contains: Alprazolam…0.5mg
	Diary No. Date of R & I & fee	Dy.No 16313 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alprazolam 0.5 mg Tablets of M/s Heal Pharma Peshawar, 079391
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for consideration on its turn.	
1560.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Meromark 1g Dry Injection I/V
	Composition	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem…1g
	Diary No. Date of R & I & fee	Dy.No 16322 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Meronem I.V Injection 1gm of M/s ICI Pakistan Ltd Karachi 018548
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial.
	Decision: Deferred for consideration on its turn.	
1561.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Vortex 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide…20mg
	Diary No. Date of R & I & fee	Dy.No 16318 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form-5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	Non- pharmacopoeial. Me- too could not be confirmed.
	Decision: Deferred for consideration on its turn.	
1562.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Mentine 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Memantine HCl…10mg"
	Diary No. Date of R & I & fee	Dy. No 10887 dated 05-03-2019 Rs.50,000 Dated 05-03-2019
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK

	Me-too status	Namentec 10mg Tablet of M/s Pharmatech Karachi (Reg.# 075937)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1563.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name + Dosage Form + Strength	Bonst 70mg Tablet
	Composition	"Each Tablet Contains: Alendronate as Sodium eq. to Alendronate acid……70mg"
	Diary No. Date of R & I & fee	Dy. No 10920 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Ostim Tablets of M/s. Genome Pharmaceuticals (Pvt.) Ltd (Reg.# 054917)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1564.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Fluzene 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levocetirizine dihydrate…….5mg"
	Diary No. Date of R & I & fee	Dy. No 10925 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antihistamine.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Invocet tablet by M/s Aries Pharma (Reg.#078437)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1565.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Urox 500mg Capsule
	Composition	"Each Capsule Contains: Ursodeoxycholic Acid…500mg"
	Diary No. Date of R & I & fee	Dy. No 10838 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anticholelithic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by Sweden
	Me-too status	Urso Capsule 500mg by M/s AGP Karachi. (Reg#070853)

	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1566.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Tacroz Capsule 0.5mg
	Composition	"Each Capsule Contains: Tacrolimus…….0.5mg"
	Diary No. Date of R & I & fee	Dy. No 10825 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Inograf 0.5 mg capsule by Platinum Pharma (Reg.# 045490)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1567.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Fluzene 2.5mg/5ml Oral Syrup
	Composition	Each 5ml Contains: Levocetirizine dihydrate…2.5mg
	Diary No. Date of R & I & fee	Dy. No 10864 dated 05-03-2019, Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antihistamine.
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Concidol- L Syrup of M/s Convell Laboratories (Reg.#079350)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1568.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	CHR 500mg/5ml Syrup
	Composition	"Each 5ml contains: Chloral hydrate……500mg"
	Diary No. Date of R & I & fee	Dy. No 10871 dated 05-03-2019, Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Sedatives and Hypnotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by Health Canada
	Me-too status	Cedate Syrup 500mg of Xenon Pharma

	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1569.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Hyline 30/0.98/8/32mg/5ml Syrup
	Composition	Each 5ml contains: Ammonium chloride……30mg Menthol…….....0.98mg Diphenhydramine……..…8mg Aminophylline……..…32mg
	Diary No. Date of R & I & fee	Dy. No 10876 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-tussive
	Type of Form	Form-5
	Finished product Specification	Mfg. Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Reg.#073704 Adalin Syrup Sugar Free of M/s Macter, F-216, Karachi
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1570.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Irinik suspension 100/15mg per 5ml
	Composition	Each 5ml contains: Ibuprofen……..…100mg Pseudoephedrine HCl……15mg
	Diary No. Date of R & I & fee	Dy. No 10875 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Analgesic and nasal decongestant
	Type of Form	Form-5
	Finished product Specification	Mfg. Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Children's Advil Cold suspension by M/s Pfizer (Approved by USFDA)
	Me-too status	Arinac Suspension 100mg/15mg/5ml by M/s Abbott Pharma, Reg. No. 22353
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1571.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Priso 800mg Tablet
	Composition	Each delayed release tablet contains: Mesalamine……...800mg
	Diary No. Date of R & I & fee	Dy.No.10850 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Intestinal anti-inflammatory agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Mesal 800mg Tablet of M/s Highnoon Labs (Reg.#081380)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1572.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Exelon 6mg Capsule
	Composition	Each Capsule Contains: Rivastigmine as hydrogen tartrate…….6mg
	Diary No. Date of R & I & fee	Dy. No 10828 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Acetylcholinesterase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Riveme 6mg Capsule of M/s Genix Karachi (Reg.#079954)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1573.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Japtin 300mg Capsule
	Composition	Each Capsule Contains: Gabapentin…….300mg
	Diary No. Date of R & I & fee	Dy. No 10833 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Gababion 300mg Capsules of M/s Merck Marker, Karachi (Reg.#045346)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1574.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Lopium 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium……...50mg
	Diary No. Date of R & I & fee	Dy. No 10858 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Angiotensin- II Receptor Blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Pixan- 50 tablet of M/s Medipak Ltd, Lahore (Reg. # 023944)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1575.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Eplran 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Eplerenone……25mg
	Diary No. Date of R & I & fee	Dy. No 10935 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Aldosterone antagonists
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Cardise 25mg Tablet of M/s Nabiqasim Karachi (Reg.# 081037)
	GMP status	GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for confirmation of approved manufacturing facility for steroidal tablet section.	
1576.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore Contract manufacturing by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name + Dosage Form + Strength	Spasgo 40/0.04 mg Injection
	Composition	Each ampoule contains: Phloroglucinol hydrate 40mg eq. to anhydrous Phloroglucinol ……. 31.12 mg Trimethylphloroglucinol……..…0.04mg
	Diary No. Date of R & I & fee	Dy. No 11415 dated 05-03-2019 Rs.50,000/- Dated 04-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spasfon, Solution for Injection in Ampoule by M/S Teva Health, (ANSM Approved)
	Me-too status	Spasfon Injection 4ml by M/s Himont (Reg. # 018530)
	GMP status	Bio-Mark: GMP certificate based on evaluation conducted in February 2020. Bio-Lab: 18 & 23-04-2019 concluding GMP compliant status
	Remarks of the Evaluator[XIII]	M/s Bio Mark has 5 approved sections and 13 products registered for contract manufacturing.
	Decision: Approved with innovators' specifications.	
1577.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore contract manufacturing by M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name + Dosage Form + Strength	Biosteron 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dydrogesterone……..…10mg"
	Diary No. Date of R & I & fee	Dy. No 10884 dated 05-03-2019 Rs.50,000 Dated 05-03-2019
	Pharmacological Group	Progestogens

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duphaston by BGP Products (Swissmedic Approved)
	Me-too status	Duphaston by Abbott (Reg. No. 006654)
	GMP status	M/s Dyson Research Laboratories: GMP certificate issued on the base of inspection conducted on 11-01-2019. M/s Bio Mark Pharma: GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	• M/s Dyson Research Laboratories has approved Tablet Hormone section • M/s Bio Mark has 5 approved sections and 13 products registered for contract manufacturing.
	Decision: Approved with USP specifications.	
1578.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore contract manufacturing by M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name + Dosage Form + Strength	Broceton E2 3mg Tablet
	Composition	"Each Vaginal Tablet Contains: Dinoprostone…….3mg"
	Diary No. Date of R & I & fee	Dy. No 10883 dated 05-03-2019 Rs.50,000 Dated 05-03-2019
	Pharmacological Group	Prostaglandins
	Type of Form	Form-5
	Finished product Specification	Mfg. specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Preg-E2 Tablets by Werrick (Reg. No. 040659)
	GMP status	M/s Dyson Research Laboratories: GMP certificate issued on the base of inspection conducted on 11-01-2019. M/s Bio Mark Pharma: GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	• M/s Dyson Research Laboratories has approved Tablet Hormone section. • M/s Bio Mark has 5 approved sections and 13 products registered for contract manufacturing.
	Decision: Deferred for following reasons: • **Applied pharmacological group.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
1579.	Name and address of manufacturer/ Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore contract manufacturing by M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name + Dosage Form + Strength	Estramark 2gm/35mcg Tablet
	Composition	"Each Film Coated Tablet Contains: Cyproterone Acetate…2mg Ethinyloestradiol……35mcg"
	Diary No. Date of R & I & fee	Dy.No 10887 dated 05-03-2019 Rs.50,000 Dated 05-03-2019
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Co-cyprindiol 2000/35 microgram Film-coated Tablets of MHRA approved
	Me-too status	Acne-Heal Tablet by M/s OBS (Reg# 073476)

	GMP status	M/s Dyson Research Laboratories: GMP certificate issued on the base of inspection conducted on 11-01-2019. M/s Bio Mark Pharma: GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator[XIII]	• M/s Dyson Research Laboratories has approved Tablet Hormone section • M/s Bio Mark has 5 approved sections and 13 products registered for contract manufacturing.
	Decision: Approved with innovators' specifications.	

b. Deferred cases

1580	Name and address of manufacturer/ Applicant	M/s StandPharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Citin 250mg injection
	Composition	Each ampoule contains: Citicoline Sodium eq. to Citicoline …….250mg
	Diary No. Date of R & I & fee	Dy.No.17177; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Psycho-stimulant and nootropic
	Type of Form	Form- 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	1's & 5's (2ml) & Rs. 206/- ampoule
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Citicoline Injection 250mg of M/s Allied Pharmaceuticals Karachi 021957
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	The official monograph of the applied formulation is not available in USP and BP. The evidence of the applied formulation in the reference regulatory authorities could not be confirmed.
	Previous decision	Deferred in 285th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC-XIII	Firm has submitted reference of ANSM; France, which is verified.
	Decision: Approved with innovators' specifications.	
1581	Name and address of manufacturer/ Applicant	M/s StandPharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Citin 500mg injection
	Composition	Each ampoule contains: Citicoline Sodium eq. to Citicoline …….500mg
	Diary No. Date of R & I & fee	Dy.No.17178; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Psycho-stimulant and nootropic
	Type of Form	Form- 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	1's & Rs. 310/ ampoule
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Citicoline Injection 500mg of M/s Allied Pharmaceuticals Karachi 021958
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.

	Previous Remarks of the Evaluator	The official monograph of the applied formulation is not available in USP and BP. The evidence of the applied formulation in the reference regulatory authorities could not be confirmed.
	Previous decision	Deferred in 285th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC-XIII	Firm has submitted reference of ANSM; France, which is verified.
	Decision: Approved with innovators' specifications.	
1582	Name and address of manufacturer/ Applicant	M/s StandPharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Citin 1g injection
	Composition	Each ampoule contains: Citicoline Sodium eq. to Citicoline ……1g
	Diary No. Date of R & I & fee	Dy.No.17179; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Psycho-stimulant and nootropic
	Type of Form	Form- 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	1's & Rs. 400/ ampoule
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Neurolin Injection 1g of M/s Global Pharmaceuticals, Islamabad 026632
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	The official monograph of the applied formulation is not available in USP and BP. The evidence of the applied formulation in the reference regulatory authorities could not be confirmed.
	Previous decision	Deferred in 285th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC-XIII	Firm has submitted reference of **Citicolina 1000mg/ 4ml injectable solution of M/s Sandoz SPA** (Spain) which has been verified.
	Decision: Approved with innovators' specifications.	
1583	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Vita-3 250mg
	Composition	Each Tablet Contains: Nicotinic Acid (Niacin)…….250mg
	Diary No. Date of R & I & fee	Dy.No.8250 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Peripheral vasodilator/ Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60 90 120 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nicosur 250mg Tab of Zafa Karachi 011956
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML.
	Previous Remarks of the Evaluator	Reference could not be confirmed BP

	Previous decision	Deferred in 295th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC-XIII	Firm has submitted TGA; Australia reference as Nicotinic acid uncoated tablet 250mg which has been verified.
	Decision: Approved with BP specifications.	
1584	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Vita 3 500mg
	Composition	Each Tablet Contains: Nicotinic Acid……500mg
	Diary No. Date of R & I & fee	Dy.No.8249 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Peripheral vasodilator/ Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nicosur 500mg Tab of M/s Zafa Karachi 011957
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML.
	Previous Remarks of the Evaluator	Reference could not be confirmed BP
	Previous decision	Deferred in 295th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC-XIII	Firm has submitted USFDA reference as Niacor uncoated tablet 500mg which has been verified.
	Decision: Approved with BP specifications.	
1585	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Bivodil 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Nebivolol as HCl……...10mg
	Diary No. Date of R & I & fee	Dy.No.8248 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved as uncoated tablet
	Me-too status	Nebivol Tablet of Tabros Pharma (Pvt) Ltd, Karachi 061532
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML.
	Previous Remarks of the Evaluator	MHRA Approved as uncoated tablet Non pharmacopoeial.
	Previous decision	Deferred in 295th DRB meeting for revision of formulation as per the reference product along with submission of requisite fee.
	Evaluation by PEC-XIII	Firm has submitted coating reference of USFDA which could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1586	Name and address of manufacturer/ Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd, F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Flusten Powder for Oral Suspension 40mg/ml

	Composition	Each 5ml contains: Fluconazole……200mg
	Diary No. Date of R & I & fee	Dy.No.35733; 29-10-2018; Rs.50,000 (29-10-2018)
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 3750/- for 35ml & as per DRAPs policy
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed in the applied strength (50mg/ 5ml is available)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	General Dry powder suspension section is available in the firm as mentioned in the submitted section approval letter. Me- too status could not be verified in the applied strength.
	Previous decision	Deferred in 293rd DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	Firm has submitted whole Form-5 again but has not submitted me-too status for which the drug was previously deferred.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1587	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Cefotam Injection 250mg
	Composition	Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……...250mg
	Diary No. Date of R & I & fee	Dy. No. 7688; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250mg/vial (10ml) & Rs. 110/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Baxim Injection 250mg of M/s Nabi Qasim (Reg. # 027201)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	• 5% overage is applied. • The official monograph of the applied formulation is available in USP. • Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th DRB meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Justification of the applied 5% overage.
	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020.

		For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug.
	Decision: Approved with BP specifications.	
1588	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Cefotam Injection 500mg
	Composition	Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……...500mg
	Diary No. Date of R & I & fee	Dy. No. 7690; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500mg/vial (10ml) & Rs. 110/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Baxim of M/s Nabi Qasim (Reg. # 027202)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	The official monograph of the applied formulation is available in USP. 5% overage is applied. Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th DRB meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Justification of the applied 5% overage.
	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020. For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug.
	Decision: Approved with BP specifications.	
1589	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Cefotam Injection 1g
	Composition	Each vial contains: Cefotaxime Sodium eq. to Cefotaxime……..1g
	Diary No. Date of R & I & fee	Dy. No. 7689; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1g/vial (10ml) & Rs. 276/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Baxim Injection 1g of M/s Nabi Qasim (Reg. # 027203)

	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	The official monograph of the applied formulation is available in USP. 5% overage is applied. Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th DRB meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Justification of the applied 5% overage.
	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020. For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug.
	Decision: Approved with BP specifications.	
1590	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Hidin injection 250mg
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine..250mg
	Diary No. Date of R & I & fee	Dy. No. 7686; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 1 vial & Rs. 44/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA
	Me-too status	Velosef injection 250mg of M/s Squibb (Reg. # 001870)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	International availability of the applied formulation could not be confirmed. 5% overage is applied. The official monograph of the applied formulation is available in BP. Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th DRB meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Justification of the applied 5% overage.

	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020. For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug. Firm could not submit RRA reference of the applied drug. I/M or I/V? Applied volume?
	Decision: Deferred for approval status in Reference Regulatory Authorities.	
1591	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Hidin injection 500mg
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine ……..…..500mg
	Diary No. Date of R & I & fee	Dy. No. 7687; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500mg x 1's vial & Rs. 58/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA
	Me-too status	Velosef injection 500mg of M/s Squibb (Reg. # 001866)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	International availability of the applied formulation could not be confirmed. 5% overage is applied. The official monograph of the applied formulation is available in BP. Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Justification of the applied 5% overage.
	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020. For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug. Firm has submitted reference of ANSM; France where both I/M and I/V are registered. I/M or I/V? Applied volume?

	Decision: Deferred for approval status in Reference Regulatory Authorities.	
1592	Name and address of manufacturer/ Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Hidin injection 1g
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine....1g
	Diary No. Date of R & I & fee	Dy. No. 7689; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	Third- generation Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1g x 1's vial & Rs. 107/- or as per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA
	Me-too status	Velosef injection 1g of M/s Squibb (Reg. # 001869)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Remarks of the Evaluator	International availability of the applied formulation could not be confirmed. 5% overage is applied. The official monograph of the applied formulation is available in BP. Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous decision	Deferred in 285th meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Justification of the applied 5% overage.
	Evaluation by PEC-XIII	Copy of GMP certificate has been submitted based on the evaluation conducted on 24-01-2020. For Justification of the applied 5% overage, firm has replied: For these product USP specifications, 90- 110% are the assay limits. We are adding 5% just to make it sure that patients get 100% activity of the product even at the time of expiry. In case, if DRAP policy does not allow us to add overages, then we will not include it in the formulation of our drug. Firm has submitted reference of ANSM; France where both I/M and I/V are registered. I/M or I/V? Applied volume?
	Decision: Deferred for approval status in Reference Regulatory Authorities.	
1593	Name and address of manufacturer/ Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Irosak tablet 150mg
	Composition	Each film-coated tablet contains: Elemental iron as iron polymaltose complex…150mg
	Diary No. Date of R & I & fee	Dy.No.17064; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Anti- Anaemic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & s per SRO

	Approval status of product in Reference Regulatory Authorities.	Not applicable
	Me-too status	Could not be confirmed in the applied formulation as 100mg is available
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
	Previous Remarks of the Evaluator	The evidence of applied strength of me-too status could not be verified. GMP status could not be confirmed by the report.
	Previous decision	**Deferred in 290th DRB meeting for evidence of applied formulation/ drug already approved by DRAP (generic /me-too status) along with registration number, brand name and name of firm.** **Further, Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.**
	Evaluation by PEC- XIII	Firm has submitted wrong me- too status as Ferricure Capsule of M/s S.J. & G Fazul Ellahie, Karachi 050637 while tablets are applied. Firm has submitted its latest GMP inspection report which was conducted on 03-02-2020 and the report concludes satisfactory level of GMP compliance.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1594	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Paranext C 500/65mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol……..500mg Caffeine……..65mg
	Diary No. Date of R & I & fee	Dy.No.1037 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Analgesic/ CNS Stimulant
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's, 100, 200 & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cafimol Extra Tablets of Zinta Pharmaceutical Industry, 168-Industrial Estate, Hyatabad, Peshawar 038898
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	Applied master formulation and manufacturing outline is not submitted by the firm.
	Previous decision	Deferred in 295th DRB meeting for the submission of master formulation and manufacturing outline of the drug.
	Evaluation by PEC- XIII	Now the firm has submitted the master formulation and manufacturing outline of the applied drug.
	Decision: Approved.	
1595	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Trimax 10/160/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate……..10mg Valsartan……160mg Hydrochlorothiazide……..25mg

	Diary No. Date of R & I & fee	Dy.No.41036 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge- HCT 10/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069551)
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	On Form- 5 applied composition is in the strength of 20/ 160/ 25 while on fee- challan and master formulation the applied strength is 10/160/25mg. Diary number is same as that of 5/160/12.5 strength. The official monograph for the applied formulation is available in USP.
	Previous decision	Deferred in 295th DRB meeting for the justification that on Form-5, applied composition is in the strength of 20/ 160/ 25 while on fee- challan and master formulation the applied strength is 10/160/25mg.
	Evaluation by PEC- XIII	Firm has replied that due to typographic mistake, the strength of Amlodipine Besylate was written as 20mg instead of 10mg in the composition mentioned on Form- 5. Now, the firm has submitted rectified composition in Form- 5.
	Decision: Approved with USP specifications.	
1596	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form + Strength	Trimax 5/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amodipine as besilate……..…5mg Valsartan……..160mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R & I & fee	Dy.No.41036 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge- HCT 5/160/12.5mg film- coated tablets of M/s Novartis Pharma(Reg. # 069548)
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	Diary Number Is Same As That Of 10/160/25 Strength. On Form- 5 applied composition is in the strength of 20/ 160/ 12.5 while on fee-challan and master formulation the applied strength is 5/160/12.5mg. The official monograph for the applied formulation is available in USP.
	Previous decision	Deferred in 295th DRB meeting for the justification that on Form-5, applied composition is in the strength of 20/ 160/ 12.5 while on fee- challan and master formulation the applied strength is 5/160/12.5mg.
	Evaluation by PEC- XIII	Firm has replied that due to typographic mistake, the strength of Amlodipine Besylate was written as 20mg instead of 5mg in the composition mentioned on Form- 5. Now, the firm has submitted rectified composition in Form- 5.
	Decision: Approved with USP specifications.	

1597	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form + Strength	Trimax 5/160/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate……5mg Valsartan…….160mg Hydrochlorothiazide……..25mg
	Diary No. Date of R & I & fee	Dy.No.41033 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge- HCT 5/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069549)
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	The official monograph for the applied formulation is available in USP. On Form- 5 applied composition is in the strength of 20/ 160/ 25 while on fee- challan and master formulation the applied strength is 5/160/25mg.
	Previous decision	Deferred in 295th DRB meeting for the justification that on Form-5, applied composition is in the strength of 20/ 160/ 25 while on fee- challan and master formulation the applied strength is 5/160/25mg.
	Evaluation by PEC- XIII	Firm has replied that due to typographic mistake, the strength of Amlodipine Besylate was written as 20mg instead of 5mg in the composition mentioned on Form- 5. Now, the firm has submitted rectified composition in Form- 5.
	Decision: Approved with USP specifications.	
1598	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form + Strength	Trimax 10/320/25mg Tablet
	Composition	Each film coated tablet contains: Amlodipine as besilate…..10mg Valsartan……..…320mg Hydrochlorothiazide…...…25mg
	Diary No. Date of R & I & fee	Dy.No.41032 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Exforge HCT 10/320/25mg of M/s Novartis Pharma 069552
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	The official monograph for the applied formulation is available in USP. On Form- 5 applied composition is in the strength of 20/ 320/ 25 while on fee- challan and master formulation the applied strength is 10/320/25mg.
	Previous decision	Deferred in 295th DRB meeting for the justification that on Form-5, applied composition is in the strength of 20/ 320/ 25 while on fee- challan and master formulation the applied strength is 10/320/25mg.

	Evaluation by PEC- XIII	Firm has replied that due to typographic mistake, the strength of Amlodipine Besylate was written as 20mg instead of 10mg in the composition mentioned on Form- 5. Now, the firm has submitted rectified composition in Form- 5.
	Decision: Approved with USP specifications.	
1599	Name and address of manufacturer/ Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Tragenol tablet 37.5mg/ 325mg
	Composition	Each film-coated tablet contains: Tramadol HCl……37.5mg Paracetamol ……325mg
	Diary No. Date of R & I & fee	Dy.No.17058; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Analgesic / Anti-pyretic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultracet tablets of Janssen Pharmaceuticals (USFDA Approved)
	Me-too status	Tonoflex P of M/s Sami Pharma (Reg. # 067163)
	GMP status	GMP report submitted does not possess any date and the report concludes : "A detailed re-inspection would be conducted in operational mode in order to assess GMP compliance as at the moment unit was completely found non- operational."
	Previous Remarks of the Evaluator	GMP report has no date and is not conclusive. Firm has general tablet section.
	Previous decision	Deferred in 285th DRB meeting for updated status of GMP of the firm form QA & LT division as the inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC- XIII	Firm has submitted its latest inspection report dated 03-02-2020 concluding satisfactory level of GMP compliance of the firm.
	Decision: Approved.	
1600	Name and address of manufacturer/ Applicant	M/s Swiss Pharmaceuticals (Pvt) Ltd. Plot No. A-159, S.I.T.E., Super Highway, Karachi.
	Brand Name + Dosage Form + Strength	Vomloc Tablet 10mg/ 10mg
	Composition	Each film-coated tablet contains: Doxylamine Succinate..…10mg Pyridoxine HCl……...10mg
	Diary No. Date of R & I & fee	Dy. No.7737; 01-03-2018; Rs. 20,000 (28-02-2018)
	Pharmacological Group	Anti- Anaemic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xonvea 10 mg/10 mg gastro-resistant tablets of M/s Alliance Pharma (MHRA Approved)
	Me-too status	Xyquil DR Tablet (Delayed- Release) of M/s Sami (R.#076469)
	GMP status	Last GMP inspection was conducted on18-10-2018 and the report concludes good GMP compliance.
	Previous Remarks of the Evaluator	• Firm has General tablet section as mentioned in the submitted inspection report. • Firm has claimed USP specifications while the official monograph for the applied formulation is not available in USP or BP.

		• The applied formulation is approved in MHRA as gastro resistant & film-coated tablet while it is applied as film coated only. • Me- too status is also of Delayed-release tablet.
	Previous decision	Deferred in 290th DRB meeting for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Evaluation by PEC- XIII	**Firm has revised its label claim and master formulation** according **to the reference but has not submitted fees for revision of formulation i.e. Rs. 5000/-.**
	Previous Decision: **Deferred in 293rd DRB meeting for submission of requisite fees for revision of formulation according to the reference.** **Second evaluation** by PEC- XIII**: Firm has submitted Rs. 5000/- for revision of formulation.**	
	Decision: Deferred for submission of	
1601	Name and address of manufacturer/ Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C.I-20, Sector 6-B, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tazox 250mg /Vial Injection (I.V)
	Composition	Each Vial of Dry Substance Contains: Ceftriaxone Sodium Eq. to Ceftriaxone ……... 250mg
	Diary No. Date of R & I & fee	Dy.No.39137 dated 28-11-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Cephalosporins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As Per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Aventriax 250mg Injection of M/s. Sanofi Aventis (Pakistan) Ltd 050376
	GMP status	Last GMP Inspection was conducted on 04-03-2019 and the report concludes that the firm was working under good level of GMP compliance.
	Previous Remarks of the Evaluator	Cephalosporin Dry Powder Injection Section is available in the firm as mentioned in the submitted GMP inspection report
	Previous decision	Deferred in 293rd DRB meeting for the confirmation of already registered drugs in the name of applicant.
	Evaluation by PEC- XIII	Firm has replied: Following injection was registered of the same product but it was an I/M injection Fitobid 250mg injection I/M (Reg.# 048879) Now we have applied I/V injection of same formulation.
	Decision: Approved.	
1602	Name and address of manufacturer/ Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C.I-20, Sector 6-B, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tazox 500mg / Vial Injection (I.V.)
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium Eq. to Ceftriaxone ……. 500mg
	Diary No. Date of R & I & fee	Dy.No.39138 dated 28-11-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Cephalosporins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As Per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Aventriax 500mg Injection of M/s. Sanofi Aventis (Pakistan) Ltd 050377
	GMP status	Last GMP Inspection was conducted on 04-03-2019 and the report concludes that the firm was working under good level of GMP compliance.
	Previous Remarks of the Evaluator	Cephalosporin Dry Powder Injection Section is available in the firm as mentioned in the submitted GMP inspection report.
	Previous decision	Deferred in 293rd DRB meeting for the confirmation of already registered drugs in the name of applicant.
	Evaluation by PEC- XIII	Firm has replied: Following injection was registered of the same product but it was an I/M injection Fitobid 500mg injection I/M (Reg.# 048880) Now we have applied I/V injection of same formulation.
	Decision: Approved.	
1603	Name and address of manufacturer/ Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C.I-20, Sector 6-B, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tazox 1g / Vial Injection (I.V.)
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium Eq. to Ceftriaxone …… 1g
	Diary No. Date of R & I & fee	Dy.No.39139 dated 28-11-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Cephalosporins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As Per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Aventriax 1g Injection of M/s. Sanofi Aventis (Pakistan) Ltd 050379
	GMP status	Last GMP Inspection was conducted on 04-03-2019 and the report concludes that the firm was working under good level of GMP compliance.
	Previous Remarks of the Evaluator	Cephalosporin Dry Powder Injection Section is available in the firm as mentioned in the submitted GMP inspection report.
	Previous decision	Deferred in 293rd DRB meeting for the confirmation of already registered drugs in the name of applicant.
	Evaluation by PEC- XIII	Firm has replied: Following injection was registered of the same product but it was an I/M injection Fitobid 1g injection I/M (Reg.# 048881) Now we have applied I/V injection of same formulation.
	Decision: Approved.	
1604	Name and address of manufacturer/ Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C.I-20, Sector 6-B, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tazox 2g / Vial Injection (I.V.)
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium Eq. to Ceftriaxone …… 2g
	Diary No. Date of R & I & fee	Dy.No.39140 dated 28-11-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Cephalosporins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As Per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Triax 2g Injection of M/s Wilshire Laboratories (Reg. # 071571)
	GMP status	Last GMP Inspection was conducted on 04-03-2019 and the report concludes that the firm was working under good level of GMP compliance
	Previous Remarks of the Evaluator	Cephalosporin Dry Powder Injection Section is available in the firm as mentioned in the submitted GMP inspection report.
	Previous decision	Deferred in 293rd DRB meeting for the confirmation of already registered drugs in the name of applicant.
	Evaluation by PEC- XIII	Firm has replied: We have applied I/V injection of same formulation being registered to us already but they were of different strengths (250mg, 500mg & 1g) and were I/M.
	Decision: Approved.	
1605	Name and address of manufacturer/ Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C.I-20, Sector 6- B, Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Mentazil tablet 10mg
	Composition	Each film- coated tablet contains: Memantine HCl ……...…….. 10mg
	Diary No. Date of R & I & fee	Dy.No.39136 dated 28-11-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Anti- Dementia Drug
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	2 x 10's & As Per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Contine 10mg Tablet of M/s Lexicon (Reg. # 055962)
	GMP status	Last GMP Inspection was conducted on 04-03-2019 and the report concludes that the firm was working under good level of GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted GMP report. • Initially, uncoated was applied while is approved in MHRA as film- coated. • Firm has revised applied formulation as film- coated and has submitted requisite fees for revision of 0formulation (Rs. 5000/-).
	Previous decision	Deferred in 293rd DRB meeting for the confirmation of already registered drugs in the name of applicant.
	Evaluation by PEC- XIII	Firm has replied that this drug has been applied for the first time.
	Decision: Approved.	
1606	Name and address of manufacturer/ Applicant	M/s Espoir Pharmaceutical, Laboratory Complex, University Road, Karachi
	Brand Name + Dosage Form + Strength	Vidogip tablets 50mg
	Composition	Each film- coated tablet contains: Vildagliptin ……....50mg
	Diary No. Date of R & I & fee	Dy.No.7182;26-02-2018; Rs.20,000/- (23-02-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	2x 14's & As per DRAP policy

	Approval status of product in Reference Regulatory Authorities.	Galvus (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pty Ltd. TGA Approved
	Me-too status	V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908)
	GMP status	Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection.
	Previous Remarks of the Evaluator	Firm has General Tablet section as mentioned in the submitted GMP inspection report. Firm has applied as film- coated tablet while the formulation is approved in reference regulatory authority as uncoated tablet. No USP or BP monograph is available for the applied formulation.
	Previous decision	Deferred in 288th DRB for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.
	Evaluation by PEC- XIII	Firm has revised the **manufacturing outline according to reference but needs to submit the requisite fees for revision of formulation.**
	Decision: Deferred for **submission of requisite fees for revision of formulation.**	
1607	Name and address of manufacturer/ Applicant	M/s Espoir Pharmaceutical, Laboratory Complex, University Road, Karachi.
	Brand Name + Dosage Form + Strength	Maxicam tablet 7.5mg
	Composition	Each film- coated tablet contains: Meloxicam ……7.5mg
	Diary No. Date of R & I & fee	Dy.No.7180;26-02-2018; Rs.20,000/- (23-02-2018)
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	10's & as per brand leader
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Artex un-coated tablet of M/s Pharmedic (Reg. # 023939)
	GMP status	Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection.
	Previous Remarks of the Evaluator	Firm has General Tablet section as mentioned in the submitted GMP inspection report. The applied formulation is approved as uncoated in USFDA and dispersible in MHRA while the firm has applied the formulation as film-coated tablet. No USP or BP monograph is available for the applied formulation.
	Previous decision	Deferred in 288th DRB for revision of formulation as per reference product along with submission of requisite fee for change of formulation.
	Evaluation by PEC- XIII	Firm has revised the **manufacturing outline according to reference but needs to submit the requisite fees for revision of formulation.**
	Decision: Deferred for **submission of requisite fees for revision of formulation.**	
1608	Name and address of manufacturer/ Applicant	M/s Espoir Pharmaceutical, Laboratory Complex, University Road, Karachi.
	Brand Name + Dosage Form + Strength	Maxicam tablet 15mg

	Composition	Each film- coated tablet contains: Meloxicam …….15mg
	Diary No. Date of R & I & fee	Dy.No.7181;26-02-2018; Rs.20,000/- (23-02-2018)
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	10's & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Artex un-coated tablet of M/s Pharmedic (Reg. # 023940)
	GMP status	Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection.
	Previous Remarks of the Evaluator	Firm has General Tablet section as mentioned in the submitted GMP inspection report. The applied formulation is approved as uncoated in USFDA and dispersible in MHRA while the firm has applied the formulation as film-coated tablet. No USP or BP monograph is available for the applied formulation.
	Previous decision	**Deferred in 288th DRB meeting for revision of formulation as per reference product along with submission of requisite fee for change of formulation.**
	Evaluation by PEC- XIII	Firm has revised the **manufacturing outline according to reference but needs to submit the requisite fees for revision of formulation.**
	Decision: Deferred for submission of requisite fees for revision of formulation.	
1609	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt. Ltd, Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan.
	Brand Name + Dosage Form + Strength	Bluphen tablet 10mg
	Composition	Each tablet contains: Methylphenidate Hydrochloride……..10mg
	Diary No. Date of R & I & fee	Dy.No.39133;28-11-2018;Rs.20,000(28-11-2018)
	Pharmacological Group	CNS Stimulant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Hynidate tablet 10mg of M/s Safe Pharma (Reg. # 053053)
	GMP status	Last GMP inspection was conducted on 19-07-2019 and the report concludes satisfactory level of cGMP with grant of GMP certificate.
	Previous Remarks of the Evaluator	Firm has General Tablet section as mentioned in the submitted GMP report of the firm.
	Previous decision	**Deferred in 293rd DRB meeting for confirmation of manufacturing facility of Psychotropic drugs.**
	Evaluation by PEC- XIII	Firm has submitted copy of DML and GMP certificate showing psychotropic tablet section.
	Decision: Approved.	
1610	Name and address of manufacturer/ Applicant	M/s Albro Pharma Private Limited, 340- S Industrial state, Kot Lakhpat, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Accred tablet 100mg
	Composition	Each film- coated tablet contains: Diclofenac Sodium……....100mg
	Diary No. Date of R & I & fee	Dy.No.37497; 13-11-2018; Rs.20,000 (09-11-2018)
	Pharmacological Group	NSAIDs

	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed as film- coated (enteric- coated is available in USFDA)
	Me-too status	Sintral SR tablet 100mg of M/s Neomedix Pharma (Reg. # 081413)
	GMP status	Last GMP inspection was conducted on 30-05-2019 and the report concludes: "Based on the area inspected, people met, the documents reviewed and considering the findings of the inspection, the firm M/s Albro Pharma is complying most of the GMP guidelines under Drugs Act, 1976 and DRAP Act, 2012. However, the deficiencies pointed out were discussed with the management and the firm has agreed to submit corrective actions taken with in stipulated time period. Moreover, as per last inspection report it was maintained that the Licensing Board in its 245th Meeting held on 22-02-2016, directed the firm to purchase land of at least 4 kanals in 6 months and complete facility within a period of two years. In compliance the firm has purchased a land of 12 Kanals and 18 Marlas in District Kasur, which was approved vide DRAP, Islamabad letter No F.14/2018-Lic dated 06-03-2019. However, the firm may be asked to provide the status of new facility, so that the unit could be shifted with in stipulated time period."
	Previous Remarks of the Evaluator	In USFDA, it is enteric- coated while in the applied master formulation it is applied as film- coated.
	Previous decision	**Deferred in 293rd DRB meeting for revision of formulation as per reference product along with submission of requisite fee.**
	Evaluation by PEC- XIII	Firm has submitted **revision of formulation as per reference product along with submission of requisite fee i.e. Rs. 5000/-.**
	Decision: Deferred for submission of remaining fees of revision of formulation i.e. Rs. 15000/-.	
1611	Name and address of manufacturer/ Applicant	M/s Pharmasol (Pvt.) Ltd, Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Cinatasol tablet 1mg
	Composition	Each film- coated tablet contains: Cinitapride as hydrogen tartrate …..……1mg
	Diary No. Date of R & I & fee	Dy.No.35903; 30-10-2018; Rs.20,000 (29-10-2018)
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 50's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Spain as uncoated tablet
	Me-too status	Cinita tablets 1mg of M/s Novamed Pharma (Reg. # 064845)
	GMP status	Last GMP inspection was conducted on 03-4-10-2017 and the report concludes grant of Drug Manufacturing License for 27 Sections.
	Previous Remarks of the Evaluator	The applied formulation is non- pharmacopoeial. Applied as film- coated tablet while approved in Spain as uncoated tablet.
	Previous decision	Deferred in 293rd DRB meeting as the formulation is applied as film-coated tablet while it is approved in reference regulatory authority (Spain) as uncoated tablet.
	Evaluation by PEC- XIII	Firm has submitted **revision of formulation as per reference product along with submission of requisite fee i.e. Rs. 5000/-.**

	Decision: Approved with innovator's specifications.	
1612	Name and address of manufacturer/ Applicant	M/s Standpharm Pakistan (Pvt) Limited, 20-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Acrol capsule 0.5mg
	Composition	Each capsule contains: Tacrolimus as Monohydrate …….0.5mg
	Diary No. Date of R & I & fee	Dy. No.30469; 10-09-2018; Rs.20,000/- (04-09-2018)
	Pharmacological Group	Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3x 10's & Rs.27.45/- per capsule
	Approval status of product in Reference Regulatory Authorities	Adoport 0.5mg hard capsules of M/s Sandoz Limited (MHRA Approved)
	Me-too status	Inograf 0.5mg capsule of M/s Platinum Pharma (Reg. # 045490)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• The firm has General capsule section as mentioned in the GMP report. • According to GMP inspection report, firm was advised to enhance the efficiency of temperature, pressure and relative humidity control system in the General capsule section.
	Previous decision	**Deferred in 290th DRB meeting for updated GMP inspection report as firm was advised to enhance the efficiency of temperature, pressure and relative humidity control system in the General capsule section.**
	Evaluation by PEC- XIII	• Firm has now submitted its latest GMP inspection report dated 18-02-2020 and the report concludes renewal of DML. • General capsule section is available in the firm as mentioned in the submitted copy of DML.
	Decision: Approved.	
1613	Name and address of manufacturer/ Applicant	M/s Standpharm Pakistan (Pvt) Limited, 20-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Acrol capsule 1mg
	Composition	Each capsule contains: Tacrolimus as Monohydrate ……....1mg
	Diary No. Date of R & I & fee	Dy. No.30470; 10-09-2018; Rs.20,000/- (04-09-2018)
	Pharmacological Group	Immuno-suppressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3x 10's & Rs. 46/- per capsule
	Approval status of product in Reference Regulatory Authorities	Adoport 1mg hard capsules of M/s Sandoz Limited (MHRA Approved)
	Me-too status	Inograf 1mg capsule of M/s Platinum Pharma (Reg. # 045491)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	The firm has General capsule section as mentioned in the GMP report. According to GMP inspection report, firm was advised to enhance the efficiency of temperature, pressure and relative humidity control system in the General capsule section.
	Previous decision	**Deferred in 290th DRB meeting for updated GMP inspection report as firm was advised to enhance the**

		efficiency of temperature, pressure and relative humidity control system in the General capsule section.
	Evaluation by PEC- XIII	Firm has now submitted its latest GMP inspection report dated 18-02-2020 and the report concludes renewal of DML. General capsule section is available in the firm as mentioned in the submitted copy of DML.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1614	Name and address of manufacturer/ Applicant	M/s Standpharm Pakistan (Pvt) Limited, 20-Km Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	Acrol capsule 5mg
	Composition	Each capsule contains: Tacrolimus as Monohydrate …….....5mg
	Diary No. Date of R & I & fee	Dy. No.30471; 10-09-2018; Rs.20,000/- (04-09-2018)
	Pharmacological Group	Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & Rs. 247.059/- per capsule
	Approval status of product in Reference Regulatory Authorities	Adoport 5mg hard capsules of M/s Sandoz Limited (MHRA Approved)
	Me-too status	Inograf 5mg capsule of M/s Platinum Pharma (Reg. # 045492)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	The firm has General capsule section as mentioned in the GMP report. According to GMP inspection report, firm was advised to enhance the efficiency of temperature, pressure and relative humidity control system in the General capsule section.
	Previous decision	**Deferred in 290th DRB meeting for updated GMP inspection report as firm was advised to enhance the efficiency of temperature, pressure and relative humidity control system in the General capsule section.**
	Evaluation by PEC- XIII	Firm has now submitted its latest GMP inspection report dated 18-02-2020 and the report concludes renewal of DML. General capsule section is available in the firm as mentioned in the submitted copy of DML.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1615	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin-A 5/40 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate…….5mg Telmisartan……..40mg
	Diary No. Date of R & I & fee	Dy.No 29718; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as bilayered
	Me-too status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma

		(Reg.# 066943)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter. Manufacturing facility needs to be confirmed. The official monograph for the applied formulation is available in USP.
	Previous decision	**Deferred in 293rd DRB meeting for the following:** **Evidence of purchase of required manufacturing equipment i.e. tablet bi- layered machine as reference product is a bi-layer tablet.**
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents.**	
1616	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- A 5/80 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate…….5mg Telmisartan……..80mg
	Diary No. Date of R & I & fee	Dy.No.29719; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Reg.# 066944)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • Manufacturing facility needs to be confirmed. • The official monograph for the applied formulation is available in USP. • On Form- 5, another strength 40mg & 10mg is mentioned.
	Previous decision	• **Deferred in 293rd DRB meeting for the following: Evidence of purchase of required manufacturing equipment i.e. tablet bi- layered machine as reference product is a bilayer tablet.** • **On Form- 5, another strength 40mg & 10mg is mentioned while applied strength is 5mg/ 80 mg.**
	Evaluation by PEC- XIII	• Firm has corrected the applied strength as **5mg/ 80 mg on Form- 5.**

		• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents..**	
1617	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin-A 10/40 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate……...10mg Telmisartan……..40mg
	Diary No. Date of R & I & fee	Dy.No 29720; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 10mg + 40mg tablet of M/s Getz Pharma (Reg.# 066945)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter. Manufacturing facility needs to be confirmed. The official monograph for the applied formulation is available in USP. On Form- 5, another strength 40mg & 5mg is mentioned.
	Previous decision	**Deferred in 293rd DRB meeting for the following:** **Evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet.** **On Form- 5, another strength 40mg & 5mg is mentioned while applied strength is 10mg/ 40 mg.**
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • Firm has corrected the applied strength as **10mg/ 40 mg on Form- 5.** • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents.**	
1618	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Telmisin-A 10/80 mg tablet
	Composition	Each tablet contains: Amlodipine as Besylate……...10mg Telmisartan……..80mg

	Diary No. Date of R & I & fee	Dy.No.29721 ; 05-09-2018;Rs.20,000 (05-09-2018)
	Pharmacological Group	Angiotensin- II Receptor Antagonist /Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Amtas 10mg + 80mg tablet of M/s Getz Pharma (Reg.# 067472)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • Manufacturing facility needs to be confirmed. • Revise label claim as bi-layered. • The official monograph for the applied formulation is available in USP. • On Form- 5, another strength 40mg & 5mg is mentioned.
	Previous decision	**Deferred in 293rd DRB meeting for the following:** • **Evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet.** • **On Form- 5, another strength 40mg & 5mg is mentioned while applied strength is 10mg/ 80 mg.**
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • Firm has corrected the applied strength as **10mg/ 80 mg on Form- 5.** • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents.**	
1619	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- D 40/12.5 mg Tablet
	Composition	Each tablet contains: Telmisartan……..40mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy.No.29722; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Telsarta- D 40/12.5 tablet of M/s Pharm Evo (Reg. # 061915)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted section approval letter.

		The official monograph for the applied formulation is available in USP. Manufacturing facility needs to be confirmed. Revise label claim as bi-layered.
	Previous decision	**Deferred in 293rd DRB meeting for evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet.**
	Evaluation by PEC- XIII	Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. But firm has not revised the master formulation as bi- layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents.**	
1620	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Telmisin- D 80/12.5 mg Tablet
	Composition	Each tablet contains: Telmisartan……..80mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy.No.29723; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Telsarta- D 80/12.5 tablet of M/s Pharm Evo (Reg. # 061914)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter. • The official monograph for the applied formulation is available in USP. • Manufacturing facility needs to be confirmed. • Revise label claim as bi-layered.
	Previous decision	**Deferred in 293rd DRB meeting for evidence of purchase of required manufacturing equipment i.e. tablet bilayered machine as reference product is a bilayer tablet**
	Evaluation by PEC- XIII	• Firm has submitted purchase slip of ZP-33 Rotary Tablet Press Machine (Bi- layered) from Munawar Bhatti Engineering Works, Lahore at Rs. 35,32,500/-. • But firm has not revised the master formulation as bi-layered tablet and requisite fees needs to be submitted for revision of formulation.
	Decision: Deferred for following reasons: • **Revision of formulation as per reference product i.e bi- layered tablet.** • **Submission of requisite fees for revision of formulation.** • **Submission of IQ, OQ and PQ documents.**	
1621	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Leveon Plus Tablet
	Composition	Each film- coated tablet contains: Levodopa……150mg

		Carbidopa……37.50mg Entacapone……200mg
	Diary No. Date of R & I & fee	Dy.No.29711; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Obsonerv 37.5/150/200mg tablet of M/s OBS Pakistan (Reg. # 070443)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• Salt is not complete because Carbidopa as monohydrate will come. • No official monograph is available for the applied formulation. • Methylene Chloride is added in the coating solution of the formulation. • General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Previous decision	**Deferred in 293rd DRB meeting for the following reasons:** **□ Applied composition is not complete because Carbidopa "as Monohydrate" is approved in reference regulatory authority.** **□ Applying a banned excipient "Methylene Chloride" in the coating solution of the applied formulation.**
	Evaluation by PEC- XIII	• Firm has revised its Form- 5 and master formulation as "Carbidopa as Monohydrate". • Firm has excluded methylene chloride in the applied formulation.
	Decision: Approved with innovator's specifications.	
1622	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Levocard tablet
	Composition	Each film- coated tablet contains: Levodopa……100mg Carbidopa…….…...……25mg Entacapone…….200mg
	Diary No. Date of R & I & fee	Dy.No.29712; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Obsonerv 25/100/200mg tablet of M/s OBS Pakistan (Reg. # 070444)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	Salt is not complete because Carbidopa as monohydrate will come. No official monograph is available for the applied formulation. Methylene Chloride is added in the coating solution of the formulation. General tablet section is available in the firm as mentioned in the submitted section approval letter.

	Previous decision	**Deferred in 293rd DRB meeting for the following reasons:** **□ Applied composition is not complete because Carbidopa "as Monohydrate" is approved in reference regulatory authority.** **□ Applying a banned excipient "Methylene Chloride" in the coating solution of the applied formulation.**
	Evaluation by PEC- XIII	• Firm has revised its Form- 5 and master formulation as "Carbidopa as Monohydrate". • Firm has again mentioned methylene chloride in the applied formulation.
	Decision: Deferred for clarification for using Methylene Chloride which is a banned excipient.	
1623	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Levocard tablet
	Composition	Each film- coated tablet contains: Levodopa……..200mg Carbidopa……..….50mg Entacapone…….200mg
	Diary No. Date of R & I & fee	Dy.No.29713; 05-09-2018; Rs.20,000 (05-09-2018)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Obsonerv 50/200/200mg tablet of M/s OBS Pakistan (Reg. # 070441)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Previous Remarks of the Evaluator	• Salt is not complete because Carbidopa as monohydrate will come. • No official monograph is available for the applied formulation. • Methylene Chloride is added in the coating solution of the formulation. • General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Previous decision	**Deferred in 293rd DRB meeting for the following reasons:** **□ Applied composition is not complete because Carbidopa "as Monohydrate" is approved in reference regulatory authority.** **□ Applying a banned excipient "Methylene Chloride" in the coating solution of the applied formulation.**
	Evaluation by PEC- XIII	• Firm has revised its Form- 5 and master formulation as "Carbidopa as Monohydrate". • Firm has excluded methylene chloride in the applied formulation.
	Decision: Approved with innovator's specifications.	
1624	Name and address of manufacturer/ Applicant	M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name + Dosage Form + Strength	Dixitol capsule 30mg
	Composition	Each capsule contains: Duloxetine HCl……..30mg
	Diary No. Date of R & I & fee	Dy.No.37831 dated 15-11-2018 Rs.20,000/- Dated 15-11-2018
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Duloxwrd 30 mg capsules of M/s Welwrd Pharma (Reg. # 076815)
	GMP status	Last GMP inspection was conducted on 20-12-2017 and the panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at the earliest.
	Previous Remarks of the Evaluator	• Source of pellets, CoA of manufacturer, stability data of pellets and GMP certificate of source of pellets is not submitted. • "As" HCl is approved in reference. • The official monograph for the applied formulation is available in USP. • Letter was issued to the firm on 13th December, 2019 but still the firm has not replied yet.
	Previous decision	**Deferred in 293rd DRB meeting for following reasons:-** **□ Source of pellets along with stability studies data, CoA of manufacturer, GMP certificate of supplier and differential fee in case of import of pellets.** **□ "Duloxetine HCl" is applied while Duloxetine "as" HCl is approved in reference regulatory authorities.**
	Evaluation by PEC- XIII	• Firm has submitted source of pellets as M/s Vision Pharma, Islamabad and all the related documents have been submitted by the firm regarding pellets. • Moreover, firm has corrected the applied composition as Duloxetine as HCl in Form- 5 and master formulation.
	Decision: Approved with USP specifications.	
1625	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	Lespra Capsule 30mg
	Composition	Each delayed release capsule contains: Lansoprazole……...30mg
	Diary No. Date of R & I & fee	Dy.No 41230 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Drugs for peptic ulcer and GORD (PPIs)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's, 40's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Lanzac 30mg Capsules Don Valley Pharmaceuticals Lahore 020293
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	All the data related to pellets is needed. General capsule section is available in the firm as mentioned in the submitted section approval letter. The official monograph for the applied formulation is available in USP.
	Previous decision	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.

	Evaluation by PEC- XIII	Firm has submitted source of pellets as M/s Vision Pharma, Islamabad and all the related documents have been submitted by the firm regarding pellets.
	Decision: Approved with USP specifications.	
1626	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	Qosmet XR 100/1000 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin as phosphate Monohydrate …100mg Metformin HCl…1000mg
	Diary No. Date of R & I & fee	Dy.No.39924 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 100/1000 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084651
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Previous decision	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.
	Evaluation by PEC- XIII	Firm has to submit stability studies data.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1627	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	Qosmet XR 50/500 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin as phosphate Monohydrate ……..50mg Metformin HCl…….500mg
	Diary No. Date of R & I & fee	Dy.No 39922 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/500 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084649
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Previous decision	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.
	Evaluation by PEC- XIII	Firm has to submit stability studies data.

	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1628	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name + Dosage Form + Strength	Qosmet XR 50/1000 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin……50mg Metformin HCl……...…1000mg
	Diary No. Date of R & I & fee	Dy.No 39923 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/1000 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084650
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Previous decision	Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.
	Evaluation by PEC- XIII	Firm has to submit stability studies data.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1629	Name and address of manufacturer/ Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name + Dosage Form + Strength	Itocon OD Tablets 150mg
	Composition	Each Film Coated Tablet Contains: Itopride HCl……150mg
	Diary No. Date of R & I & fee	Dy.No 7546 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Itop S.R 150mg Tablet Nexus Pharma, Karachi 070883
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance**. T**he panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Previous Remarks of the Evaluator	The applied formulation is non- pharmacopoeial.
	Previous decision	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC- XIII	Firm says: It is to clarify that we applied for the aforesaid drug on 21st February, 2019 after confirmation from the minutes of 288th

		meeting of registration Board in which Itopride as HCl 150mg tablets are approved to M/s Invictus Pharmaceuticals (Page 309 of minutes of 288th DRB meeting attached). But unfortunately, this decision was reversed and the case was deferred in 291st DRB meeting held in September 2019. Clearly, DRAP has committed a mistake in this case so it is our humble request to allow us to submit another dossier against the fee- challan used for Itocon OD tablets as we are not liable to lose 20,000 PKR for the mistake that is not even committed by us. It is, therefore, requested to kindly forward our request to concerned authority and oblige.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1630	Name and address of manufacturer/ Applicant	**M/s Wilson's Pharmaceuticals, 387-388, I-9 Industrial Area, Islamabad.**
	Brand Name + Dosage Form + Strength	**Coldene day tablets**
	Composition	**Each film-coated tablet contains:** **Acetaminophen…….500mg** **Phenylephrine HCl…….....5mg**
	Diary No. Date of R & I & fee	**Dy. No. 16694, R&I Dated 02.10.2017, Rs. 20,000/- (02.10.2017)**
	Pharmacological Group	**Analgesic, Non-opioid/ Sympathomimetic Decongestants**
	Type of Form	**Form- 5**
	Finished product Specification	**Manufacturers**
	Pack size & Demanded Price	**1x 10's, 10x 10's & as per SRO**
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	**GMP inspection conducted on 24-01-2018 with conclusive remarks that firm was operating at very good level of GMP compliance at the time of inspection.**
	Previous Remarks of the Evaluator	**The local and international availability of the applied formulation could not be confirmed.**
	Previous decision	**Deferred in 284th DRB meeting as the the local and international availability of the applied formulation could not be confirmed.**
	Evaluation by PEC- XIII	• International reference has been verified as Demazin Cold + Flu Relief tablet of iNova Pharmaceuticals (Australia) Pty Ltd TGA; Australia Approved. • Me- too submitted by the firm has been verified as: Panadol CF Day Caplet (Paracetamol 500mg and **Phenylephrine HCl 5mg** of M/s GSK, Karachi 094797. • The applied formulation is on stability so firm needs to submit stability studies data of atleast three batches at accelerated and real time conditions.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1631	Name and address of manufacturer/ Applicant	M/s Wilson's Pharmaceuticals, 387-388, I-9 Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	Balance-H tablets 80/12.5mg
	Composition	Each film-coated tablet contains: Temisartan……..…80mg Hydrochlorothiazide…...12.5mg
	Diary No. Date of R & I & fee	Dy. No. 16696, R&I Dated 02.10.2017, Rs. 20,000/- (02.10.2017)

	Pharmacological Group	Antihypertensive , Angiotensin-II receptor antagonist/ A thiazide diuretic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x7's, 4x7's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as uncoated
	Me-too status	Co- telsan tablets of M/s Hilton Pharmaceuticals (Reg. # 047125)
	GMP status	GMP inspection conducted on 24-01-2018 with conclusive remarks that firm was operating at very good level of GMP compliance at the time of inspection.
	Previous Remarks of the Evaluator	Approved in MHRA as uncoated while is applied as film-coated.
	Previous decision	Deferred in 284th DRB meeting as the applied formulation is approved in MHRA as uncoated while is applied as film-coated.
	Evaluation by PEC- XIII	• Firm has submitted international reference of Micardis HCT USFDA Approved drug which is bi- layered uncoated tablet. • Firm has revised the formulation as bi- layered uncoated tablet and has provided evidence of availability of bi-layered tablet machine. • Firm has revised the applied formulation according to the reference with submission of Rs. 5000/- fees under deposit slip # 2035247 dated: 31st August, 2020.
	Decision: Approved.	
1632	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form + Strength	Raninext 150mg Tablet
	Composition	Each tablet contains: Ranitidine as Hydrochloride……150mg
	Diary No. Date of R & I & fee	Dy.No.1346 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- allergic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10, 20, 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	Ranitide 150mg Tab of M/s Siza Lahore 011747
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	On fee challan brand name is raninext but composition is glimepiride and metformin while in form- 5 and master formulation applied composition is Ranitidine MHRA Approved as film- coated while is applied as uncoated.
	Previous decision	Deferred in 295th DRB meeting for the following reasons: • Justification that on fee- challan brand name is Raninext but composition is of glimepiride and metformin. While in Form- 5 and master formulation applied composition is Ranitidine. • Clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.
	Evaluation by PEC- XIII	• Firm has replied that: o Due to typographic mistake, the composition o fee- challan was written as Glimepiride and Metformin.

		○ International reference is Zantac 150mg tablets of GSK which are uncoated tablets (according to the firm). • Submitted reference of Zantac tablets of GSK are discontinued in MHRA and are coated tablets as revealed in the SMPC of the product. • Moreover, **Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.**
	Decision: Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.	
1633	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Raninext 300mg Tablet
	Composition	Each Tablet Contains: Ranitidine as Hydrochloride……300mg
	Diary No. Date of R & I & fee	Dy.No.41347 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- allergic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10, 20, 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	Ranitide 150mg Tab of M/s Siza Lahore 011747
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	• On fee- challan brand name is raninext but composition is of glimepiride and metformin. • While in Form- 5 and master formulation applied composition is Ranitidine. • MHRA Approved as film- coated while is applied as uncoated.
	Previous decision	**Deferred in 295th DRB meeting for the following reasons:** • **Justification that on fee- challan brand name is Raninext but composition is of glimepiride and metformin. While in Form- 5 and master formulation applied composition is Ranitidine.** • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.**
	Evaluation by PEC- XIII	Firm has replied that: • Due to typographic mistake, the composition o fee-challan was written as Glimepiride and Metformin. • International reference is Zantac 150mg tablets of GSK which are uncoated tablets (according to the firm). • Submitted reference of Zantac tablets of GSK are discontinued in MHRA and are coated tablets as revealed in the SMPC of the product. • Moreover, **Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.**
	Decision: Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.	

1634	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form + Strength	Painext- K tablet 25mg
	Composition	Each film- coated tablet contains: Diclofenac potassium…..…25mg
	Diary No. Date of R & I & fee	Dy.No 41047 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Could not be confirmed in the applied strength as 50, 70 and 100mg are available
	GMP status	22-02-2018 satisfactory
	Previous Remarks of the Evaluator	Me- too Could not be confirmed in the applied strength as 50, 70 and 100mg are available.
	Previous decision	Deferred in 295th DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC- XIII	Firm has submitted me- too as: Signa 25mg tablets of M/s Valor Pharma which could not be verified.
	Decision: Deferred for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1635	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol SR Tablets 100mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……..…100mg
	Diary No. Date of R & I & fee	Dy.No.7269 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as modified- release tablet
	Me-too status	Tramed- SR Tablets of M/s Platinum Pharma 024458
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Previous Remarks of the Evaluator	Tablet section is available in the firm as mentioned in the submitted GMP certificate. TGA; Australia Approved as modified- release tablet. Me- too is also of SR Tablets.
	Previous decision	Deferred in 295th DRB meeting for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC- XIII	Firm has corrected the applied formulation as Each film- coated sustained- release tablet contains: Tramadol HCl……100mg With submission of requisite fees i.e. Rs. 5000/-.

		During second evaluation, the reference product has been found as bilayered tablet in TGA; Australia. So, firm has submitted the master formulation as modified release bilayered tablet with evidence of availability of bilayered tablet machine mentioned in the submitted GMP inspection report dated: 03-07-2009.
	Decision: Approved with innovators' specifications.	
1636	Name and address of manufacturer/ Applicant	M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bandil Suspension 100mg/5ml
	Composition	Each 5ml contains: Albendazole……..…….100mg
	Diary No. Date of R & I & fee	Dy.No 8808 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Nenzole Suspension of M/s Nenza pharmaceutical Peshawar 025891
	GMP status	Last GMP inspection was conducted on 19-09-2018 & 03-10-2018 and the report concludes fair level of GMP compliance and the panel recommends grant of cGMP certificate.
	Previous Remarks of the Evaluator	• General oral liquid section is available in the firm as mentioned in the submitted GMP inspection report. • International availability could not be confirmed. • The official monograph for the applied formulation is available in USP.
	Previous decision	**Deferred in 295th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting**.
	Evaluation by PEC- XIII	Firm has submitted international reference of EMA as Zentel 100mg/ 5ml susupension of M/s GSK which could not be verified.
	Decision: **Deferred for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting**.	
1637	Name and address of manufacturer/ Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd.Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Curoxaban 10mg Tablet
	Composition	Each film- coated Tablet Contains: Rivaroxaban…….10mg
	Diary No. Date of R & I & fee	Dy.No 44482 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rivar 10mg Tablet of Hilton Pharma Kar. 081476
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Previous Remarks of the Evaluator	The applied formulation is non- pharmacopoeial. gen tablet DML Applied master formulation is not submitted.
	Previous decision	Deferred in 295th DRB meeting for the submission of master formulation of the applied drug.
	Evaluation by PEC- XIII	Firm has submitted the applied master forrmulation in reply.

	Decision: Approved with innovators' specifications.	
1638	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	Nadal Tablets 80mg
	Composition	Each Tablet Contains: Nadolol……80mg
	Diary No. Date of R & I & fee	Dy.No 42027 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10 5x 10 10x 10 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Norgar Tablets 80mg Pulse Pharmaceutical, Mozay Badoke, Raiwind Road Lahore. 052730
	GMP status	17-10-2018 the panel unanimously recommends for grant of GMP certificate.
	Previous Remarks of the Evaluator	Attached fee- challan is of onscot 2.5mg tablet (Metolazone).
	Previous decision	Deferred in 295th DRB meeting for clarification that attached fee-challan is of Onscot 2.5mg tablet (Metolazone).
	Evaluation by PEC- XIII	Now, the firm has submitted relevant yellow copy of paid fee-challan under deposit slip # 0803995 against the concerned applied drug.
	Decision: Approved.	
1639	Name and address of manufacturer/ Applicant	M/s Vision Pharmaceuticals, Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Colistin Dry Powder sachet I million IU
	Composition	Each Vial Contains: lyophilized powder Colistimethate Sodium……1 Million IU
	Diary No. Date of R & I & fee	Dy.No 44470 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Colistat powder for Injection Medisure Lab, Karachi 076160
	GMP status	11-02-2019 the panel recommends the issuance of GMP certificate to Vision Pharma Islamabad as the firm is found at a good level of GMP as today.
	Previous Remarks of the Evaluator	• Sachet is written under the heading of dosage form in form- 5 while each vial contains is written under the heading of applied composition. And under the heading of proposed route of administration injection is written. • Firm has lyophilized section. • Are they making powder by themselves or they will refill the imported powder.
	Previous decision	Deferred in 295th DRB meeting for following: • Clarification of applied dosage form as sachet or injection. • If injection is applied then clarification is required regarding lyophilised powder that are they making powder by themselves or they will refill the powder imported from outside.
	Evaluation by PEC- XIII	Firm has submitted the reply as: • Sachet was written mistakenly. Actually, the applied drug is a dry powder injection and is filled in vials. Corrected Form- 5 is submitted.

		• We will import the powder in ready to fill containers and refill in vials only.
	Decision: Deferred for submission of requisite fees for change of applied dosage form from sachet to injection.	
1640	Name and address of manufacturer/ Applicant	M/s Werrick Pharmaceuticals, Plot No. 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	Flueze Extra Day tablets
	Composition	Each film coated tablet contains: Acetaminophen……..500mg Phenylephrine hydrochloride…….5mg
	Diary No. Date of R & I & fee	Dy. No. 17521; 09-10-2017; Rs.20,000/- (109-10-2017)
	Pharmacological Group	Analgesic/ Decongestant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Contac Cold + Flu by Canada
	Me-too status	Could not be confirmed
	GMP status	21-09-2017; GMP and follow up inspection Firm is operating at acceptable level of GMP compliance.
	Previous Remarks of the Evaluator	International availability and Me too could not be confirmed.
	Previous decision	Deferred in 284th DRB meeting as the the local and international availability of the applied formulation could not be confirmed.
	Evaluation by PEC- XIII	• International reference has been verified as Demazin Cold + Flu Relief tablet of iNova Pharmaceuticals (Australia) Pty Ltd TGA; Australia Approved. • Me- too submitted by the firm has been verified as: Panadol CF Day Caplet (Paracetamol 500mg and **Phenylephrine HCl 5mg** of M/s GSK, Karachi 094797. • The applied formulation is on stability so firm needs to submit stability studies data of atleast three batches at accelerated and real time conditions.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
1641	Name and address of manufacturer/ Applicant	**M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.**
	Brand Name + Dosage Form + Strength	**Paradol 37.5mg/ 325mg Tablets**
	Composition	Each film-coated tablet contains:- Tramadol Hydrochloride…….37.5mg Acetaminophen…….325mg
	Diary No. Date of R & I & fee	**Dy.No.19406; 28-05-2018; Rs.20,000 (28-05-2018)**
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tramadoln Plus Tablet 37.5/ 325mg of M/s Akson Pharma (Reg. # 085459
	GMP status	**Last GMP inspection was conducted on 13-11-2018 and th report concludes grant of DML.**
	Previous Remarks of the Evaluator	• Tablet section (General) is available in the firm as mentioned in the submitted inspection report. • Firm's previous address was M/s Benson

		Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB.
	Previous decision	Deferred in 291st DRB meeting for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.
	Evaluation by PEC- XIII	• Firm has submitted copy of DML along with DRAP's letter confirming the change of premises under same DML no. • Copy of GMP certificate is attached. • Original deposit slip evidencing the payment of additional fee of Rs. 20,000/- has been submitted by the firm under deposit slip no. 0827131 dated 08-04-2020.
	Decision: Approved.	

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

1642	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt. Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio- Clozine 30 Powder
	Composition	Each 100 gram contains: Sulfaclozine Sodium……..…30g
	Diary No. Date of R & I & fee	Dy.No.1169 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Anti- coccidial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g & Decontrolled
	Me- too status	E- Cox Oral Powder of M/s Biogen Pharma, Rawat 057033
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1643	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio Lincospec 100 Powder
	Composition	Each gram contains: Lincomycin HCl…….……33.3g Spectinomycin……66.7g
	Diary No. Date of R & I & fee	Dy.No.1168 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.

	Remarks of the Evaluator[XIII]	• Firm has submitted me- too status in reply as Linco-spectin 100 Reg. # 009991 of M/s Zoetis, Ghazi Brothers which could not be verified.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1644	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Noxyflor oral powder
	Composition	Each gram contains: Florfenicol……100mg Oxytetracycline HCl……..…300mg Neomycin sulphate……150mg
	Diary No. Date of R & I & fee	Dy.No.1158 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg & Decontrolled
	Me- too status	E- Col Water Soluble Powder of M/s Evergreen Pharmaceuticals, Lahore 081733
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1645	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Flormax- C Powder
	Composition	Each gram contains: Florfenicol…….……..…23g Colistin sulphate……50MIU
	Diary No. Date of R & I & fee	Dy.No.1159 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator[XIII]	• Me- too could not be confirmed as powder. • Now, the firm wants to change the dosage form from powder to liquid with following composition: Each 100ml contains: Florfenicol…….....……..…23g Colistin sulphate……..……50MIU
	Decision: Deferred for submission of changed formulation from powder to liquid with submission of requisite fees.	
1646	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio- Enro Plus Powder
	Composition	Each gram contains: Enrofloxacin…….…….75mg Sulphamethoxy Pyridazine……..……..75mg Sulphamethazine……..…….50g Trimethoprim…….25mg

	Diary No. Date of R & I & fee	Dy.No.1170 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator[XIII]	Firm has submitted in reply the following me- too: Cina T.S Oral Suspension Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad 031456; which is of oral suspension, while they have applied oral powder. So, me- too status could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1647	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio Fosfotyl Powder
	Composition	Each gram contains: Fosomycin Calcium….....20mg Tylosin tartrate.....…100mg Fructose….....180mg Sodium Phosphate…….……150mg
	Diary No. Date of R & I & fee	Dy.No.2042 dated 16-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator[XIII]	Firm has submitted the following me- too in reply: Fosfo- 20 Oral Powder of M/s Evergreen Pharmaceuticals, Ferozpur Road, Lahore (Reg. # 088861); which could not be verified.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1648	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio Furazone 24.4% Powder
	Composition	Each gram contains: Furazolidone…….24.4%
	Diary No. Date of R & I & fee	Dy.No.1165 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Nitro furans
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1kg & Decontrolled
	Me- too status	Reothin-H Feed Supplement of M/s Delux Chemical Industries Karachi 023406
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.

	Remarks of the Evaluator[XIII]	
	Decision: Deferred as formulation is under review.	
1649	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Oxycloz Plus Drench
	Composition	Each gram contains: Oxfendazole……62.50mg Oxyclozanide……..22.65mg Cobalt Sulphate……1.67mg Sodium Selenite……0.50mg
	Diary No. Date of R & I & fee	Dy.No.442 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me- too status	Punch Drench of M/s Selmore Pharma (Pvt) Ltd., Lahore 032206 if each 100ml contains is applied.
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator[XIII]	Applied as drench while gm/ mg is applied in composition.
	Decision: Deferred for following reasons: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Formulation is applied as drench while gm/ mg is applied in composition.**	
1650	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Clozasol Gold Drench
	Composition	Each 100ml contains: Levamisole (HCl)…….3gm Oxyclozanide……..……..6gm Cobalt Sulphate…….0.334gm Sodium Selenite……..…0.1gm
	Diary No. Date of R & I & fee	Dy.No.438 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator[XIII]	• On application, following formulation is applied: • Each ml contains: Oxfendazole……..94mg Oxyclozanide…….……34mg Cobalt Sulphate……..…3.82mg Sodium Selenite……..……0.50mg • Me- too status could not be confirmed.
	Decision: Deferred for following reasons: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Different compositions have been applied in different parts of dossier.**	
1651	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Clozasol Plus Drench
	Composition	Each 100ml contains:

		Levamisole (HCl)……1.50gm Oxycloazanide……..3gm Cobalt Sulphate……..…0.167gm Sodium Selenite……...0.05gm
	Diary No. Date of R & I & fee	Dy.No.444 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator[XIII]	Me- too could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1652	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Combimit Drench
	Composition	Each ml contains: Oxyclozanide .....94mg Oxfendazole.....34mg Cobalt sulphate.....3.82mg Sodium selenite.....0.50mg
	Diary No. Date of R & I & fee	Dy.No.443 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml,1000ml & Decontrolled
	Me- too status	Combiox Drench of M/s Selmore Pharma (Pvt.) Ltd Multan Road Lahore 057004
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator[XIII]	On Form- 5, Clozasol Gold Drench brand name is applied while fee- challan is of Combimit Drench.
	Decision: Deferred for applied composition as on Form- 5, "Clozasol Gold Drench" brand name is applied while fee- challan is of "Combimit Drench".	
1653	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Doximit- C Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate….....25,00,000 IU Tylosin as Tartrate….....100mg Doxycycline as Hyclate….....100mg Bromhexine as HCl.....…5mg
	Diary No. Date of R & I & fee	Dy.No.439 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Mucolytic / Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator[XIII]	Me- too could not be confirmed.

	Decision: Deferred for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1654	Name and address of manufacturer/ Applicant	**M/s Divine Pharmaceuticals, Plot No. 226-A, Sundar Industrial estate, Lahore.**
	Brand Name + Dosage Form + Strength	Broment Fort (Oral Solution)
	Composition	Each ml contains: Bromhexine HCl…….…. 2.5% w/v
	Diary No. Date of R & I & fee	Dy.No.31029 dated 14-09-2018 Rs.20,000/-Dated 14-09-2018
	Pharmacological Group	Mucolytic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	**Not provided**
	Remarks of the Evaluator[XIII]	• GMP report is not submitted. • Me- too status could not be confirmed. • General Liquid Vet section is available in the firm as mentioned in the submitted DML.
	Decision: Deferred for following reasons: • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1655	Name and address of manufacturer/ Applicant	**M/s Divine Pharmaceuticals, Plot No. 226-A, Sundar Industrial Estate, Lahore.**
	Brand Name + Dosage Form + Strength	G- Flor Water Soluble Powder
	Composition	Each kg contains: Florfenicol…….. 20% w/w
	Diary No. Date of R & I & fee	Dy.No.2600 dated 24-02-2017 Rs.20,000/-Dated 23-02-2017
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g, 250g, 500g, 1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	**Not provided**
	Remarks of the Evaluator[XIII]	• GMP report is not submitted. • Me- too status could not be confirmed. • General Powder Vet section is available in the firm as mentioned in the submitted DML.
	Decision: Deferred for following reasons: • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1656	Name and address of manufacturer/ Applicant	**M/s Divine Pharmaceuticals, Plot No. 226-A, Sundar Industrial estate, Lahore.**
	Brand Name + Dosage Form + Strength	G- Flor Plus Water Soluble Powder
	Composition	Each kg contains: Florfenicol…….. 25% w/w
	Diary No. Date of R & I & fee	Dy.No.2598 dated 24-02-2017 Rs.20,000/-Dated 23-02-2017
	Pharmacological Group	Anti- bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	100g, 250g, 500g, 1kg & Decontrolled
	Me- too status	Could not be confirmed
	GMP status	**Not provided**
	Remarks of the Evaluator[XIII]	• GMP report is not submitted. • Me- too status could not be confirmed. • General Powder Vet section is available in the firm as mentioned in the submitted DML.
	Decision: Deferred for following reasons: • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

b. Deferred Cases

1657	Name and address of manufacturer/ Applicant	M/s Nawan Laboratories Pvt Ltd. 136 sector 15 Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Cefanil IMM injector (Intramammary suspension)
	Composition	Each 8gm syringe contains: Cefquinome as Sulfate……75mg
	Diary No. Date of R & I & fee	Dy. No.24004;11-07-2018; Rs.20,000 (10-07-2018)
	Pharmacological Group	Anti- bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Cobac 7.5 % LA Injection of M/s Mylab (Pvt) Ltd. (Reg. # 073911)
	GMP status	Last GMP inspection report was conducted on 30-04-018 and the report concludes satisfactory level of GMP compliance.
	Previous Remarks of the Evaluator[XIII]	• Liquid Injectable Veterinary (Cephalosporin) section is available in the firm.
	Previous decision	• Deferred in 291st DRB meeting for confirmation of manufacturing facility of PFS.
	Evaluation by PEC-XIII	• Instead of submitting the required query which was the confirmation of manufacturing facility of PFS, firm claims that the applied product has another me-too as "Cobactan LC Intramammary of M/s ICI Pakistan with Reg. # 078220." • The above submitted me- too could not be verified.
	Decision: Deferred in 293rd DRB meeting for confirmation of manufacturing facility of Pre- filled Syringe. Second Evaluation: Firm has submitted the following reply. 1- Cefanil IMM Injector (Intramammary Suspension) will be manufactured under aseptic condition in approved Cephalosporin Sterile Liquid Section Veterinary (copy of section approval enclosed). 2- The Filling is carried out under laminar flow hood in class 100 in pre-sterilized IMM plastic Disposable Flexi-Tube using semi auto manual filling machine. During filling fill-weight is periodically checked and recorded. 3- Packing is carried outside on packaging belt. The IMM Plastic Disposable Flexi-Tubes are labelled and sealed in polythene bags and finally pack in printed carton. In the light of above explanation you are request to kindly approve our applied drug "Cefanil IMM Injector (Intramammary Suspension)". We hope that you will consider our request in this regard and for this we shall be very thankful to you.	
	Decision: Referred to Licensing Division for confirmation of manufacturing facility.	

1658	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36- Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Vital Plus Powder
	Composition	Each kg contains: Vitamin-A……10 MIU Vitamin-D3……3 MIU Vitamin-E……5000 MIU Vitamin-K3……3000 MIU Vitamin-C……30,000 MIU
	Diary No. Date of R & I & fee	Dy. No.25079; 19-07-2018; Rs.20,000(19-07-2018)
	Pharmacological Group	Multi- Vitamin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg, 2.5kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Advet Plus Water Soluble Powder of M/s Medicure Labs (Reg. # 019929)
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Previous Remarks of the Evaluator[XIII]	Veterinary Oral powder is available in the firm as is mentioned in the submitted GMP inspection report.
	Previous decision	Deferred in 291st DRB meeting for clarification regarding solubility of vitamins as formulation has both water soluble and fat soluble vitamins.
	Evaluation by PEC-XIII	Firm has replied: "Finished form of the said product is in powder form not in the liquid form and it is not water soluble but dispersible."
	Decision: Approved with innovators' specifications.	
1659	Name and address of manufacturer/ Applicant	M/s Breeze Pharma Pvt. Ltd, Plot No. 125, 126, 127-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Biodran Powder
	Composition	Each gm contains: Propionic Acid Calcium……250mg Propionic Acid Sodium…..……..250mg Acetanilide……..……150mg Magnesium Oxide……..……125mg Iron-II Sulphate……..…….0.40mg Magnesium Sulphate……..….0.20mg Copper Sulphate……..……0.10mg Cobalt Sulphate……..…….0.40mg Sodium Chloride……..……..20mg Sodium Molybdate……..……0.10mg
	Diary No. Date of R & I & fee	Dy.No.36004; 30-10-2018; Rs.20,000 (30-10-2018)
	Pharmacological Group	Digestive tonic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-08-2017 and the report concludes reasonable satisfactory level of compliance. The firm was advised to submit compliance report within 30 days of inspection.
	Previous Remarks of the Evaluator[XIII]	• General Oral powder section is available in the firm as mentioned in the submitted GMP inspection report.

		• Me- too status could not be confirmed. • Firm has submitted the following reference which could not be verified. *"Diarroban Powder of M/s Star Labs Lahore (Reg. # 026438)."*
	Previous decision	Deferred in 293rd DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	• Firm has now changed its applied formulation as : Each 12gm Water soluble powder contains: Neomycin sulphate……..…400mg Streptomycin sulphate……...400mg Sulphaguanidine……....4g Vitamin-A Acetate……80,000 IU Kaolin…….... 4g Pectin…… 400mg Bismuth subnitrate…. ……...2g • Firm has submitted Rs. 20,000/-dated 27-08-2020 under deposit slip # 2032154 for change of formulation. • Applied pack size is now 100g, 250g, 500g, 1kg, 5kg, 10kg, and 25kg. • Verified me- too is Diarroban powder of Star Labs Reg. # 026438.
	Decision: Registration Board rejected the case firm has changed its application wrt ingredients.	
1660	Name and address of manufacturer/ Applicant	M/s Breeze Pharma Pvt. Ltd, Plot No. 125, 126, 127-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Ivoron Super Gold Injection I/M, I/V, S/C
	Composition	Each ml contains: Ivermectin……20mg Clorsulon……100mg
	Diary No. Date of R & I & fee	Dy.No.36007; 30-10-2018; Rs.20,000 (30-10-2018)
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-08-2017 and the report concludes reasonable satisfactory level of compliance. The firm was advised to submit compliance report within 30 days of inspection.
	Previous Remarks of the Evaluator[XIII]	• General injection section is available in the firm as mentioned in the submitted GMP inspection report. • Me- too status could not be confirmed. • Firm has submitted the following me- too but it could not be verified: *"Iver Gold Super Injection of M/s Cherished Pharmaceuticals, Lahore (Reg. # 058806."*
	Previous decision	**Deferred in 293rd DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Evaluation by PEC-XIII	• Firm has now changed its applied formulation as : Ivoron Super Gold Injection I/M, S/C Each ml contains: Ivermectin… 20mg

		Clorsulon….. 10mg • Firm has submitted Rs. 20,000/-dated 27-08-2020 under deposit slip # 2032153 for change of formulation. • Applied pack size is now 50ml. • Verified me- too is Ivoclor injection of Nawal Pharma Reg. # 078244.
	Decision: Approved with innovators' specifications.	
1661	Name and address of manufacturer/ Applicant	M/s Breeze Pharma Pvt. Ltd, Plot No. 125, 126, 127- A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Clobendol- 12 Drench
	Composition	Each 100ml contains: Albendazole……..…10gm Closental……2gm
	Diary No. Date of R & I & fee	Dy.No.35999; 30-10-2018; Rs.20,000 (30-10-2018)
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-08-2017 and the report concludes reasonable satisfactory level of compliance. The firm was advised to submit compliance report within 30 days of inspection.
	Previous Remarks of the Evaluator[XIII]	• General Oral liquid section is available in the firm as mentioned in the submitted GMP inspection report. • Me- too status could not be confirmed.
	Previous decision	**Deferred in 293rd DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Evaluation by PEC-XIII	• Firm has submitted the following me- too that has been verified as: "*Clobendol Suspension of M/s Vety- Care Pharmaceuticals (Pvt.) Ltd., Islamabad (Reg. # 028523)".*
	Decision: Approved with innovators' specifications.	
1662	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tylodoxin Plus Soluble Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate……200gm Doxycycline HCl……..…400gm Colistin sulphate……...…500 MIU Bromhexine HCl……..…5gm
	Diary No. Date of R & I & fee	Dy.No 1887 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.

	Previous Remarks of the Evaluator[XIII]	Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report Me- too could not be confirmed.
	Previous decision	Deferred in 295th DRB meeting for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	Firm has changed its applied formulation as follows: Each 1000gm contains: Tylosin Tartrate……200gm Doxycycline HCl……..…400gm Colistin sulphate……...…500 MIU Bromhexine HCl……...…10gm Following me- too has been verified for the changed formulation: Dox- 40 water soluble powder of M/s Nawal Pharma, Taxilla, Rawalpindi Reg. # 074096. Firm has submitted Rs. 5000/- fees under slip # 0798068 dated: 26-08-2020 for revision of formulation.
	Decision: Deferred for submission of differential fees for revision of strength of Bromhexine HCl.	
1663	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	CNF-250 Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline HCl……..100gm Neomycin Sulphate……30gm Furaltadone HCl…….75gm
	Diary No. Date of R & I & fee	Dy.No 1886 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Trifle Powder Selmore Pharmaceuticals (Pvt) Ltd., Lahore 029615
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	• Neomycin "as" Sulphate is available in me- too. • Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report.
	Previous decision	Deferred in 295th DRB meeting as "Neomycin Sulphate" is applied while it is approved as Neomycin "as" Sulphate.
	Evaluation by PEC-XIII	Firm has corrected the applied composition in reply as "Neomycin as Sulphate."
	Decision: Deferred for Furaltadone containing formulations are under review.	
1664	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflox- Plus Soluble Powder
	Composition	Each 1000gm contains: Florfenicol…..150gm Chlortetracycline HCl…..150gm
	Diary No. Date of R & I & fee	Dy.No.1885 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	Me- too could not be confirmed Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report
	Previous decision	Deferred in 295th DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	Firm has changed its applied formulation as follows: Each 1000gm contains: Florfenicol…….……...150gm Oxytetracycline HCl…..…….……...150gm Following me- too has been verified for the changed formulation: Enteroflor oral powder of M/s Hawk Bio Pharma, Rawat, Islamabad Reg. # 078399. Firm has submiited Rs. 5000/- fees under slip # 0798069 dated: 26-08-2020 for revision of formulation.
	Decision: Registration Board rejected as firm has changed its application as Chlortetracycline HCl has been changed with Oxytetracycline HCl.	
1665	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflotin Oral Solution
	Composition	Each 100ml Contains: Florfenicol…23gm Colistin Sulphate…50 MIU
	Diary No. Date of R & I & fee	Dy.No.1892 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500ml, 1 litre & Decontrolled
	Me-too status	Flotin Liquid D-Maarson Pharmaceuticals, Plot # 17, Street SS-2, National Industrial Zone, Rawat, Islamabad. 072680
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	Oral liquid vet section needs to be verified.
	Previous decision	Deferred in 295th DRB meeting for confirmation of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC-XIII	Oral Liquid Syrup Vet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved with innovators' specifications.	
1666	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noa- Esel Super Oral Solution
	Composition	Each 100ml Contains: Vitamine E……15gm Sodium Selenite Pentahydrate…0.20gm Vitamin C……...0.40gm

		Zinc Sulphate……...……1gm
	Diary No. Date of R & I & fee	Dy.No 1893 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Immunity booster veterinary preparation
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500ml, 1 litre & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	Me- too could not be confirmed Firm has oral liquid syrup section as mentioned in the submitteed GMP inspection report.
	Previous decision	Deferred in 295th DRB meeting for confirmation of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC-XIII	Oral Liquid Syrup Vet section is available in the firm as mentioned in the submitted section approval letter. Firm has changed its applied formulation as follows: Each 100ml Contains: Vitamine E…….20gm Sodium Selenite Pentahydrate…0.20gm Zinc Sulphate…….0.90gm Following me- too submiited by firm has been verified as: Sel- E Solution of M/s Noble Pharma Reg. # 063641. Firm has submiited Rs. 5000/- fees under slip # 0798070 dated: 26-08-2020 for revision of formulation.
	Decision: Registration Board rejected the case firm has changed its application and excluded Vitamin C from the applied formulation.	
1667	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflox- Excel Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline HCl…….300gm Neomycin Sulphate……..…150gm Florfenicol……...100gm
	Diary No. Date of R & I & fee	Dy.No 1889 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	Me- too could not be confirmed Firm has vet powder antibiotic section as mentioned in the submitted GMP inspection report
	Previous decision	Deferred in 295th DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	Firm has changed its applied formulation as follows: Each 1000gm contains:

		Oxytetracycline HCl…..…….300gm Neomycin Sulphate……...……..…150gm Florfenicol…….……...100gm. Following me- too has been verified for the changed formulation: Vety Flor Mix Powder of M/s Leads Pharma, Islamabad (Reg. # 094484). Firm has submiited Rs. 5000/- fees under slip # 0798071 dated: 26-08-2020 for revision of formulation.
	Decision: Registration Board rejected the case as an ingredient Chlortetracycline HCl has been changed as Oxytetracycline HCl.	
1668	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	CNF Super Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline…400gm Neomycin Sulphate…120gm Furaltadone HCl…300gm
	Diary No. Date of R & I & fee	Dy.No 1888 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	N.C.Bak Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. 053905
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	• Firm has vet powder antibiotic section as mentioned in the submitted gmp inspection report. • Neomycin "as" Sulphate Is Available In Me- Too.
	Previous decision	Deferred in 295th DRB meeting as "Neomycin Sulphate" is applied while it is approved as Neomycin "as" Sulphate.
	Evaluation by PEC-XIII	Firm has corrected the applied composition in reply as "Neomycin as Sulphate."
	Decision: Deferred as Furaltadone containing formulation are under review.	
1669	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tylodoxin-Excel Oral Solution
	Composition	Each 100ml Contains: Tylosin Tartrate…20gm Doxycycline HCL…40gm Colistin sulphate…50 MIU Bromhexine hcl…500mg
	Diary No. Date of R & I & fee	Dy.No 1895 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.

	Previous Remarks of the Evaluator[XIII]	• Me- too could not be confirmed. • Oral liquid vet section needs to be verified.
	Previous decision	Deferred in 295th DRB meeting for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Confirmation of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC-XIII	Oral Liquid Syrup Vet section is available in the firm as mentioned in the submittred section approval letter. Firm has changed its applied formulation as follows: Each 100ml Contains: Tylosin Tartrate…20gm Doxycycline HCl…20gm Colistin sulphate…50 MIU Bromhexine HCl…0.5g Following me- too has been verified for the changed formulation: 1. CRD Mars Liquid of M/s D- Maarson Pharma, Islamabad (Reg. # 072677). Firm has submitted Rs. 5000/- fees under slip # 0798072 dated: 26-08-2020 for revision of formulation.
	Decision: Deferred for submission of remaining requisite fees for revision of applied strength of Doxycycline HCl.	
1670	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noatil-250 Oral Solution
	Composition	Each 100ml Contains: Tilmicosin…….25gm
	Diary No. Date of R & I & fee	Dy.No 1894 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1 litre & Decontrolled
	Me-too status	Hicos 250 Oral Solution Hilton Pharma (Pvt) Ltd., Karachi 044909
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	Oral liquid vet section needs to be verified.
	Previous decision	Deferred in 295th DRB meeting for confirmation of required manufacturing facility /section from Licensing Division.
	Evaluation by PEC-XIII	Oral Liquid Syrup Vet section is available in the firm as mentioned in the submittred section approval letter.
	Decision: Approved with innovators' specifications.	
1671	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflor-30 Oral Solution
	Composition	Each 100ml contains: Florfenicol……30gm
	Diary No. Date of R & I & fee	Dy.No.1891 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Previous Remarks of the Evaluator[XIII]	• Oral liquid vet section needs to be verified. • Me- too could not be confirmed.
	Previous decision	Deferred in 295th DRB meeting for following: • Confirmation of required manufacturing facility / section from Licensing Division. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC-XIII	Oral Liquid Syrup Vet section is available in the firm as mentioned in the submitted section approval letter. Firm has changed its applied formulation as follows: Noaflor- 25 Oral Solution Each 100ml contains: Florfenicol…..25gm Following me- too has been verified for the changed formulation: 1. Nobiflor 25% Liquid of M/s Noble Pharma, AJK (Reg. # 063639). Firm has submiited Rs. 5000/- fees under slip # 0798073 dated: 26-08-2020 for revision of formulation.
	Decision: Deferred for submission of differential requisite fees for revision of strength of Florfenicol.	

Priority Approval / Registration of Drugs during the COVID-19 Pandemic:

The world is currently facing one of the biggest public health outbreaks of coronavirus disease 2019 (COVID-19), which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The outbreak was first identified in Wuhan, Hubei, China, in December 2019. The World Health Organization (WHO) declared the outbreak to be a Public Health Emergency of International Concern on 30th January 2020 and recognized it as a pandemic on 11th March 2020. More than 723,500 cases of COVID-19 have been reported in over 190 countries and territories, resulting in approximately 34,000 deaths till date.

Many clinical trials are under way for treatment / prevention of COVID-19 which uses different type of pharmaceutical / biological drugs. Many drugs have been allowed for investigational use in hospitals under medical care for the COVID-19 patients.

The authorities from all over the world have considered the use of several drugs under their respective national emergency management plans. Clinical Management Guidelines for COVID-19 Infections issued by Ministry of National Health Services, Regulation & Coordination (available at http://covid.gov.pk/guideline) also recommends the use of these drugs in the management of mild to moderate and severe cases of COVID-19 patients. Further, USFDA has also given Emergency Use Authorization for chloroquine and hydroxychloroquine tablets for COVID-19 patients (available at: https://www.fda.gov/media/136534/download). Further Centers for disease control and prevention (CDC) USA also issued Information for Clinicians on Therapeutic Options for Patients with COVID-19 (available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html). Similarly Italian Medicines Agency (AIFA) considers it essential to provide clinical elements useful to guide the prescription and to define, for each drug used, a relationship between benefits and risks for the individual patient. *Off-label* use is only permitted under the national emergency management plan for treatment of COVID-19 by using Lopinavir / ritonavir (available at: https://www.aifa.gov.it/emergenza-covid-19).

Keeping in view the above information, Drug Regulatory Authority of Pakistan (DRAP), exercising its powers under Rule 26of Drugs (LRA) Rules amended via SRO 713(1)/2018 dated 8th June, 2018, has made following decision in its meeting dated 3rd April, 2020.

1. Allowed to submit registration application on form 5, form 5A, form 5D or form 5E instead of form 5F for following formulations as approved by the reference regulatory auhtories;
    a. Chloroquine Phosphate
    b. Hydroxychloroquine Sulfate
    c. Lopinavir/Ritonavir
    d. Oseltamivir
    e. Ascorbic Acid
2. The applicant can submit their application till 2nd May 2020 but the date was extended till 5th May, 2020 vide letter No.F.76-DRAP/2020(PE&R) dated 30th April, 2020.
3. These applications will be considered out of queue.
4. The validity of registration period for above mentioned drugs registered during this time will be one only.
5. The registration holder will submit data of product development of 3 and 6 months within one year. The data will be considered by Registration Board for extension of validity period of registration for further period.
6. Applicant shall submit affidavit for compliance of point and 5 above.

The Authority further extended the time lines till 31-07-2020 for submission of registration applications on Form 5 / Form 5-A / Form 5-D for molecules already approved by the Authority for the management of Covid-19.

1672.	Name and address of manufacturer/ Applicant	M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan
	Brand Name + Dosage Form + Strength	Delquine 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate……250mg
	Diary No. Date of R & I & fee	Dy.No.13132 dated 12/05/2020Rs. 20,000/- dated 09-06-2020
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	Resochin 250mg Tab by M/s Bayer Karachi.
	GMP status	15-08-2017 Grant of DML for Gen Tab And Cap Sections Only
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1673.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Eniqor 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate……500mg
	Diary No. Date of R & I & fee	Dy.No.13662 dated 15/06/2020; Rs. 50,000/- dated 15-06-2020
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	Could not be confirmed
	GMP status	23-04-2019 and the report concludes reasonably acceptable
	Remarks of the Evaluator[XIII]	Tab gen section is available as mentioned in GMP inspection report
	Decision: Approved.	

1674.	Name and address of manufacturer/ Applicant	M/s Pharmevo Private Limited, Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Brand Name + Dosage Form + Strength	Evoquin Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate……150mg
	Diary No. Date of R & I & fee	Dy.No.5587 dated 06/04/2020Rs. 20,000/- dated 06-04-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status	Could not be confirmed.
	GMP status	07-02-2019 issuance of GMP certificate.
	Remarks of the Evaluator[XIII]	Fee- challan is of 150mg and in Form- 5, 300mg is mentioned. And in applied master formulation strength is mentioned as 250mg. Me-too status could not be verified. International reference could not be verified.
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1675.	Name and address of manufacturer/ Applicant	M/s Citi Pharma Pvt Ltd., 3-km Head Balloki, Phool Nagar District Kasur, Pakistan
	Brand Name + Dosage Form + Strength	Chloronil 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate…...250mg
	Diary No. Date of R & I & fee	Dy.No.9219 dated 28/04/2020Rs. 20,000/- dated 28-04-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Resochin 250mg tablet of M/s Bayer (Reg. # 000025)
	GMP status	19-03-2019 renewal of DML for gen tab section
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1676.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Oclor 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate……500mg Eq. to Chloroquine Base.…300mg
	Diary No. Date of R & I & fee	Dy.No. 14297 dated 22/06/2020Rs. 50,000/- dated 22-06-2020 Form 5D
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Could not be confirmed

	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1677.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Oclor 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Chloroquine Phosphate ……250mg
	Diary No. Date of R & I & fee	Dy.No. 14296 dated 22/06/2020Rs. 20,000/- dated 22-06-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status	RESOCHIN 250MG TAB by M/s Bayer Karachi, (Reg. No. 000025)
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1678.	Name and address of manufacturer/ Applicant	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan
	Brand Name + Dosage Form + Strength	Nevquin-P 50mg/5ml Syrup
	Composition	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg
	Diary No. Date of R & I & fee	Dy.No. 8331 dated 20/04/2020Rs. 20,000/- dated 20-04-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120, 450ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Malaquin syrup of M/s Rakaposhi Pharmaceutical Ltd., Peshawar having registration no. 034687
	GMP status	19-11-2011 Renewal of DML
	Remarks of the Evaluator[XIII]	Gen syrup GMP certificate
	Decision: Approved with innovators' specifications.	
1679.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Oclor 50mg/5ml Syrup
	Composition	Each 5ml Contains: Chloroquine Phosphate…80mg Eq. to Chloroquine Base…50mg
	Diary No. Date of R & I & fee	Dy.No. 14295 dated 22/06/2020Rs. 20,000/- dated 22-06-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status	Malaquin syrup of M/s Rakaposhi Pharmaceutical Ltd., Peshawar having registration no. 034687
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1680.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries Pvt Ltd.17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Inzivir 30mg Capsule
	Composition	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…30mg
	Diary No. Date of R & I & fee	Dy.No. 18324 dated 27/07/2020Rs. 50,000/- dated 27-07-2020
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5D
	Finished product Specification	USP
	Pack size & Demanded Price	10 30 60 As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamiflu 30mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved
	Me-too status	Could not be confirmed.
	GMP status	05-08-2019 acceptable level of compliance of GMP.
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1681.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Inzivir 45mg Capsule
	Composition	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…45mg
	Diary No. Date of R & I & fee	Dy.No.18325 dated 27/07/2020Rs. 50,000/- dated 27-07-2020
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5D
	Finished product Specification	USP
	Pack size & Demanded Price	10 30 60 As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamiflu 45mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved
	Me-too status	--
	GMP status	05-08-2019 and acceptable
	Remarks of the Evaluator[XIII]	Firm has capsule gen section according to submitted DML.
	Decision: Approved.	
1682.	Name and address of manufacturer/ Applicant	M/s Nabiqasim Industries Pvt Ltd.17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Inzivir 6mg/ml Oral Suspension (Dry powder)
	Composition	Each ml of Reconstituted Suspension Contains: Oseltamivir Phosphate Eq. to Oseltamivir…6mg
	Diary No. Date of R & I & fee	Dy.No.18323 dated 27/07/2020Rs. 50,000/- dated 27-07-2020
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5D
	Finished product Specification	Innovators
	Pack size & Demanded Price	25ml, 75ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamiflu 6mg/ml for Suspension (oseltamivir as phosphate) by M/s Roche, USFDA Approved.
	Me-too status	Osemvir Powder for Oral Suspension (60mg/5ml) by M/s Brookes Pharmaceutical, reg. No. 42290
	GMP status	05-08-2019 and acceptable
	Remarks of the Evaluator[XIII]	

	Decision: Deferred for confirmation of required manufacturing facility / section "Dry Powder suspension" from Licensing Division.	
1683.	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt Ltd., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form + Strength	Pronto 6mg/ml Suspension
	Composition	Each ml Contains: Oseltamivir…6mg
	Diary No. Date of R & I & fee	Dy.No. 18326 dated 27/07/2020Rs. 50,000/- dated 27-07-2020 Form 5D
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamiflu 6mg/ml for Suspension (oseltamivir as phosphate) by M/s Roche, USFDA Approved.
	Me-too status	Osemvir Powder for Oral Suspension (60mg/5ml) by M/s Brookes Pharmaceutical, reg. No. 42290
	GMP status	08-08-2019 Acceptable
	Remarks of the Evaluator[XIII]	Section needs to be confirmed.
	Decision: Deferred for confirmation of required manufacturing facility / section "Dry Powder suspension" from Licensing Division.	
1684.	Name and address of manufacturer/ Applicant	M/s The Searle Company Limited, 32 Km, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	Ritohi Oral Solution 80/20mg
	Composition	Each oral solution contains: Lopinavir…80mg Ritonavir…20mg
	Diary No. Date of R & I & fee	Dy.No. 8843 dated 23/04/2020Rs. 20,000/- dated. 23-04-2020 Form 5
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
	GMP status	24-04-2018 satisfactory
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1685.	Name and address of manufacturer/ Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form + Strength	Lorivir Oral Solution 80/20mg
	Composition	Each ml contains: Lopinavir…80mg Ritonavir…20mg
	Diary No. Date of R & I & fee	Dy.No. 8918 dated 24/04/2020Rs. 20,000/- dated. 23-04-2020
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
	GMP status	12-09-2019 good
	Remarks of the Evaluator[XIII]	

	Decision: Approved.	
1686.	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad
	Brand Name + Dosage Form + Strength	Lopivir Oral Solution 80/20mg
	Composition	Each oral solution contains: Lopinavir…80mg Ritonavir…20mg
	Diary No. Date of R & I & fee	Dy.No.7792 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020
	Pharmacological Group	Antiviral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml, 160ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
	GMP status	24-07-2019 and report concluded that the rectification of observations report may be forwarded to competent authority fir resumption of production activities.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1687.	Name and address of manufacturer/ Applicant	M/s Winlet Pharmaceuticals, 30-km, Lahore Sargodha Road, Lahore
	Brand Name + Dosage Form + Strength	Loprit Oral Solution 80/20mg
	Composition	Each oral solution contains: Lopinavir……80mg Ritonavir…….20mg
	Diary No. Date of R & I & fee	Dy.No. 7796 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg by M/s Abbott, Reg No. 28427
	GMP status	12-12-2017 and grant of DML including liquid syrup gen section
	Remarks of the Evaluator[XIII]	Gen liquid syrup section DML.
	Decision: Approved with innovators' specifications.	
1688.	Name and address of manufacturer/ Applicant	M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form + Strength	Rilovir Oral Solution 80/20mg
	Composition	Each oral solution contains: Lopinavir…80mg Ritonavir…20mg
	Diary No. Date of R & I & fee	Dy.No. 7927 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
	GMP status	23-07-2018 satisfactory

	Remarks of the Evaluator[XIII]	Gen syrup section GMP report.
	Decision: Approved.	
1689.	Name and address of manufacturer/ Applicant	M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ritomid oral solution 80/20mg
	Composition	Each oral solution contains: Lopinavir…80mg Ritonavir…20mg
	Diary No. Date of R & I & fee	Dy.No.7772 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved
	Me-too status	Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
	GMP status	02-10-2019 satisfactory
	Remarks of the Evaluator[XIII]	Gen oral liquid section GMP report
	Decision: Approved.	
1690.	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt Ltd.124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form + Strength	Ripavir 200/50 mg Tablet
	Composition	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg
	Diary No. Date of R & I & fee	Dy.No. 18328 dated 27/07/2020Rs. 20,000/- dated 27-07-2020 Form 5
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved
	Me-too status	Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED, Reg No. 62250
	GMP status	08-08-2019 Acceptable
	Remarks of the Evaluator[XIII]	Gen tab GMP certificate
	Decision: Approved.	
1691.	Name and address of manufacturer/ Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form + Strength	Ripavir 100/25 mg Tablet
	Composition	Each Film Coated Tablet Contains: Lopinavir…..100mg Ritonavir……25mg
	Diary No. Date of R & I & fee	Dy.No. 18327 dated 27/07/2020Rs. 20,000/- dated 27-07-2020
	Pharmacological Group	Anti-viral
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Could not be confirmed.
	GMP status	08-08-2019 Acceptable
	Remarks of the Evaluator[XIII]	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

1692.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Covik 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate……200mg
	Diary No. Date of R & I & fee	Dy.No. 14293 dated 22/06/2020Rs. 20,000/- dated 22-06-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	PLAQUENIL 200mg film coated tablet by M/s Concordia, USFDA Approved
	Me-too status	HCQ 200 Tablets by M/s Getz Pharma, Reg. No. 045471
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	Gen tab GMP certificate
	Decision: Approved.	
1693.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Covik 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate……400mg
	Diary No. Date of R & I & fee	Dy.No.14294 dated 22/06/2020Rs. 20,000/- dated 22-06-2020 Form 5
	Pharmacological Group	Anti- malarial
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status	Could not be confirmed.
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	Gen tab GMP certificate
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
1694.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	Neu-C 1000mg/5ml Injection
	Composition	Each 5ml Vial contains: Ascorbic Acid……...1000mg
	Diary No. Date of R & I & fee	Dy.No. 16428 dated 08/07/2020 Rs. 50,000/- dated 08-07-2020
	Pharmacological Group	Anti- oxidant
	Type of Form	Form- 5D
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AIFA of Italy
	Me-too status	Not available in the applied strength as 500mg/ 5ml is available.
	GMP status	28-02-2019 and the report concludes fair level of GMP compliance.
	Remarks of the Evaluator[XIII]	Gen injection section GMP certificate.

	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1695.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals, 35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Immo-C 500mg Tablet
	Composition	Each Chewable Tablet Contains: Ascorbic Acid…500mg
	Diary No. Date of R & I & fee	Dy.No. 14516 dated 23/06/2020Rs. 20,000/- dated 23-06-2020
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	**Last GMP inspection conducted on 09-03-2017 and the report concludes that viewing the facts the company is following the GMP guidelines as of today.**
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1696.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name + Dosage Form + Strength	Seha 500mg Chewable Tablet
	Composition	Each Chewable Tablet Contains: Ascorbic Acid…….500mg
	Diary No. Date of R & I & fee	Dy.No.13953 dated 17/06/2020Rs. 20,000/- dated 17-06-2020
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon- 500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	Grant of GMP certificate on the basis of evaluation done on 22-11-2019.
	Remarks of the Evaluator[XIII]	Gen tab GMP certificate
	Decision: Approved with innovators' specifications.	
1697.	Name and address of manufacturer/ Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Cebion 500mg Tablet
	Composition	Each Tablet Contains: Ascorbic Acid…500mg
	Diary No. Date of R & I & fee	Dy.No.13958 dated 17/06/2020Rs. 20,000/- dated 17-06-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	26-12-2018 Renewal of DML
	Remarks of the Evaluator[XIII]	General tablet section GMP certificate.
	Decision: Approved.	

1698.	Name and address of manufacturer/ Applicant	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Cebion 1g Tablet
	Composition	Each Tablet Contains: Ascorbic Acid……...1000mg
	Diary No. Date of R & I & fee	Dy. No. 13959 dated 17/06/2020Rs. 20,000/- dated 17-06-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AIFA of Italy as Effervescent tablets
	Me-too status	C- 1000 effervescent tablets of M/s Werrick (025425)
	GMP status	26-12-2018 Renewal of DML.
	Remarks of the Evaluator[XIII]	General tablet section GMP certificate. In reference and me- too effervescent tablets are approved while applied ones are simple tablets.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
1699.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Citro-C 500mg Tablet
	Composition	Each Chewable Tablet Contains: Ascorbic Acid……..500mg
	Diary No. Date of R & I & fee	Dy.No. 13658 dated 15/06/2020Rs. 20,000/- dated 15-06-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	GMP certificate granted on the basis of evaluation done on 15-02-2019.
	Remarks of the Evaluator[XIII]	Gen tab GMP certificate
	Decision: Approved.	
1700.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt Ltd, Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form + Strength	Cee- Max 500mg/5ml Injection I/M, I/V
	Composition	Each Ampoule Contains: Ascorbic Acid…500mg/5ml
	Diary No. Date of R & I & fee	Dy.No.17870 dated 22/07/2020Rs. 20,000/- dated 22-07-2020 Form 5
	Pharmacological Group	Vitamin
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	50 ampoules x 5ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Ascorbic Acid 500 Mg Inj by M/s Schazoo
	GMP status	21-02-2019 and good

	Remarks of the Evaluator[XIII]	Sterile liquid injection ampoule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
1701.	Name and address of manufacturer/ Applicant	M/s Rasco Pharma, 5.5 Km, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Ras- C 500mg Chewable Tablet
	Composition	Each Chewable Tablet Contains: Ascorbic Acid…….500mg
	Diary No. Date of R & I & fee	Dy.No.17449 dated 17/07/2020Rs. 20,000/- dated 17-07-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin-C 500mg of M/s Abbott Khi 006119
	GMP status	04-02-2019 renewal of DML
	Remarks of the Evaluator[XIII]	• Initially, On Form- 5 in label claim firm had written chewable tablet while in master formulation they had applied film- coating. • Now, the firm has revised the applied master formulation according to the reference excluding film-coating and has submitted Rs. 5000/- fees for revision of formulation.
	Decision: Approved.	
1702.	Name and address of manufacturer/ Applicant	M/s Delta Pharma Pvt Ltd., Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan
	Brand Name + Dosage Form + Strength	Delvit- C 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Ascorbic Acid…….500mg
	Diary No. Date of R & I & fee	Dy.No.13131 dated 12/05/2020Rs. 20,000/- dated 09-06-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as uncoated tablet
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	Not provided
	Remarks of the Evaluator[XIII]	Approved in MHRA as uncoated while applied as film- coated tablet. Gen tab section DML. GMP report needs to be submitted.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.** • **Registration Board referred the case to QA & LT Division for updated GMP status of the firm.**	
1703.	Name and address of manufacturer/ Applicant	M/s Avensis Pharmaceuticals, F-24/1, Estern Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Avence- C injection 500mg/ 5ml
	Composition	Each 5ml ampoule contains: Ascorbic acid ……..500mg

	Diary No. Date of R & I & fee	Dy.No. 18316 dated 27/07/2020Rs. 20,000/- dated 27-07-2020
	Pharmacological Group	Neutraceutical
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml ampoules x 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Ascorbic Acid 500 mg by M/s Schazoo
	GMP status	31-12-2018 and new DML.
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	
1704.	Name and address of manufacturer/ Applicant	M/s Aneeb Pharmaceuticals Pvt Ltd., 24-Km Bedian Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Orbic- C 500 Tablet
	Composition	Each Tablet Contains: Ascorbic Acid……..500mg
	Diary No. Date of R & I & fee	Dy.No.8109 dated 20/04/2020Rs. 20,000/- dated 20-04-2020
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 30's & Rs. 15/ tab
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	29-10-2018 renewal of DML for gen tab and cap section only
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1705.	Name and address of manufacturer/ Applicant	M/s Iceberg Pharmaceuticals Pvt Ltd., Plot No. 144, Nowshera Indsutrial Estate, Risalpur, Kpk, Pakistan.
	Brand Name + Dosage Form + Strength	Icecon Chewable 500mg Tablet
	Composition	Each Chewable Tablet Contains: Ascorbic Acid…….500mg
	Diary No. Date of R & I & fee	Dy.No. 7920 dated 16/04/2020Rs. 20,000/- dated 16-04-2020
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	03-02-2020 and the report concludes resumption of production of activities in all sections.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1706.	Name and address of manufacturer/ Applicant	M/s Pharmedic Laboratories Pvt Ltd.,16-km, Multan Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Pharmedic Vitamin C 500mg Tablet
	Composition	Each Tablet Contains: Ascorbic Acid…….500mg
	Diary No. Date of R & I & fee	Dy.No. 8450 dated 21/04/2020Rs. 20,000/- dated 20-04-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cecon-500 (Chewable) Tab Vitamin C 500mg of M/s Abbott Khi 006119
	GMP status	Last GMP inspection was conducted opn 04-02-2020 and the report concludes satisfactory level of GMP.
	Remarks of the Evaluator[XIII]	
	Decision: Approved with innovators' specifications.	
1707.	Name and address of manufacturer/ Applicant	M/s Welmark Pharmaceuticals, Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK.
	Brand Name + Dosage Form + Strength	Wel- C 1000mg tablets
	Composition	Each effervescent tablet contains: Ascorbic Acid……....1000mg
	Diary No. Date of R & I & fee	Dy.No.15442 dated 30/06/2020 Rs. 20,000/- dated 30-06-2020 Form 5
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	1 g Effervescent Tablets of M/s Dompe Farmaceutici SPA Approved by AIFA of Italy
	Me-too status	C- 1000 Effervescent Tablets of M/s Werrick Pharma Industrial Area, Islamabad.
	GMP status	**Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and report concludes the renewal of DML.**
	Remarks of the Evaluator[XIII]	
	Decision: Approved.	

Agenda of Evaluator PEC-XIV

Review of Formulation of Orlistat with reference to Stability of the Product:

1. Status of Orlistat Capsule in RRA:

In reference regulatory authorities such as EMA and USFDA, the formulation is approved in in 60mg and 120mg Hard Gelatin Capsule. Study of innovator product (Xenical) shows that it is presented as a conventional hard gelatin capsule (size 1) containing pellets with an active substance concentration of 50%. The excipients cellulose microcrystalline (as diluent and extrusion/spheronisation aid), sodium starch glycollate (as disintegrant), sodium lauryl sulphate (as wetting agent), povidone K30 (as binder and stabiliser), and talc is added (for lubrication) to the pellets before encapsulation.

2. Assessment Report of European Medicine Agency (EMA), Procedure No. EMEA/H/C/000854/X/10 states that

Stability of the Product:

The stability studies were conducted according to the relevant ICH guidelines. 9 batches of product stored in the proposed marketing containers (with desiccant) for periods up to 36 months at 25°C/60%RH, 30°C 60%RH., 30°C /65%RH and 40°C /75%RH. It is important to underline that Orlistat has poor chemical stability at 40°C due to a low melting range (42 - 44°C) of the active substance. Based on the available stability data, the proposed shelf life is acceptable.

Hence, Stability conditions as per ICH guidelines are:

30°C ± 2°C / 65% RH ± 5% (Intermediate)

25°C ± 2°C / 65% RH ± 5% (Long term)

ICH in its guideline 2.1.7.1 (General case) also recommends the following **It is up to the applicant to decide whether long term stability studies are performed at 25 ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH.*

***If 30°C ± 2°C/65% RH ± 5% RH is the long-term condition, there is no intermediate condition.*

3. Conclusion:
As Pakistan is in climatic Zone IVA where the requirement of long-term stability is already 30°C ± 2°C / 65% RH ± 5%, so according to above evidences and keeping in view of orlistat poor chemical stability at 40°C due to a low melting range (42 - 44°C) of the active substance there will be no accelerated stability studies of orlistat at 40°C ± 2°C/75% RH ± 5% RH. Hence, it is advisable to accept stability data on intermediate condition on 30°C ± 2°C/65% RH ± 5% RH as per ICH stability guidelines. Moreover, degradation studies of pellets at long term stability conditions should be mandatory.
(Reference Link: https://www.ema.europa.eu/en/documents/scientific-discussion/xenical-epar-scientific-discussion_en.pdf)
https://www.ema.europa.eu/en/documents/variation-report/alli-h-c-854-x-0001-epar-assessment-report-extension_en.pdf.
https://www.ema.europa.eu/en/medicines/human/EPAR/alli.
https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.

Discussion: Registration board deliberated the stability of orlistat API and pellets through various review documents, public assessment reports and already submitted data by the firms. Registration Board observed that orlistat has poor chemical stability at 40°C due to low melting range (42°C - 44°C) and degradation products exceed the limits at different time points during stability studies.

Decision: Keeping in view the stability of the orlistat pellets, Registration Board directed the applicants (drug product manufacturers) to submit the source of pellets in which stability studies of the pellets have been conducted at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH alongwith quantification of degradation products throughout the stability studies / assigned shelf life.

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

1708.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAZON 1g INJECTION IV
	Composition	Each vial contains: Ceftriaxone as sodium……..1gm
	Diary No. Date of R& I & fee	3502, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	The firm has claimed BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Rezone 1gm Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031980)
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries have Dry powder Injectable (Cephalosporin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract

		manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved with USP specifications.	
1709.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAZON 500mg INJECTION IM
	Composition	Each vial contains: Ceftriaxone as sodium……..500mg
	Diary No. Date of R& I & fee	3501, 25-01-2019, 50,000/-, 24-01-2019
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	The firm has claimed BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries have Dry powder Injectable (Cephalosporin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved with USP specifications.	
1710.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAZON 250mg INJECTION IM
	Composition	Each vial contains: Ceftriaxone as sodium……..250mg
	Diary No. Date of R& I & fee	3500, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	The firm has claimed BP specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Rezone 250mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad.
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries have Dry powder Injectable (Cephalosporin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved with USP specifications.	
1711.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STACOLMI 1MIU INJECTION
	Composition	Each vial contains: Colistimethate sodium……..1MIU
	Diary No. Date of R& I & fee	3503, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	The firm has claimed USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries have Dry powder Injectable (General) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal

		routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved with USP specifications.	
1712.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	S-D3 INJECTION
	Composition	Each ml contains: Cholecalciferol (Vitamin D3)…….5mg
	Diary No. Date of R& I & fee	3506, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished product Specification	The firm has claimed EP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries has provided Liquid Injection Ampoule & vial (SVP) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved with innovator's specifications.	
1713.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAXIN 400mg CAPSULE
	Composition	Each Capsule contains: Cefixime as trihydrate…….400mg
	Diary No. Date of R& I & fee	3505, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules, for oral use by Lupin Ltd for Lupin Pharma. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule by M/s Nawan Lab. Karachi. Reg. No. 82219

	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries has provided Capsule (Cephalosporin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5. • The product is available in JP.
	Decision: Approved with JP specifications.	
1714.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAXIN 200mg/5ml SUSPENSION
	Composition	Each 5ml after reconstitution contains: Cefixime as trihydrate…….200mg
	Diary No. Date of R& I & fee	3499, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Fasxime 200mg/5ml Suspension of M/s Fassgen (Reg#053527)
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries has provided Oral Dry powder suspension section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5. • The product is available in JP.
	Decision: Approved.	

1715.	Name and address of manufacturer / Applicant	**Applicant:** M/s Stallion Pharmaceuticals (Pvt.) Ltd., 581-Sundar Industrial Estate, Lahore **Contract manufacturer:** M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	STAFER INJECTION 100mg/5ml
	Composition	Each 5ml contains: Iron Sucrose complex eq. to elemental iron…….100mg
	Diary No. Date of R& I & fee	3504, 25-01-2019, 50,000/-, 25-01-2019
	Pharmacological Group	Antianaemic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venofer of Luitpold (USFDA)
	Me-too status	Axifer of Nova Med
	GMP status	The firm M/s Stallion Pharmaceuticals was granted GMP certificate based on inspection conducted on 22-11-2018. The firm M/s English Pharmaceutical Industries was granted GMP certificate based on inspection conducted on 16-01-2018.
	Remarks of the Evaluator [XIV].	• M/s English Pharmaceutical Industries has provided Liquid Injection Ampoule & vial (SVP) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. M/s Stallion Pharmaceuticals have 4 approved sections and no product registered on contract manufacturing. • The firm had initially applied on Form-5 on 25-01-2019. Later the firm applied on CTD to avail out of queue priority. Now the firm has requested that their normal routine queue on Form-5 has been attained since the initial application was received on 25-01-2019, therefore consider our application on Form-5.
	Decision: Approved.	
1716.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Apocine Dry Suspension 100mg/5ml
	Composition	Each 5ml contains: Azithromycin as dihydrate……100mg
	Diary No. Date of R& I & fee	10949, dated 15-05-2020, 20,000/- dated 15-05-2020
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Azitma 100mg/5ml dry suspension Tablet of M/s Sami Karachi. (Reg.# 074901)
	GMP status	GMP certificate was granted based on the basis of inspection conducted on 31/07/2018.
	Remarks of the Evaluator [XIV].	
	Decision: Approved.	
1717.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan (Pvt.) Ltd. 20-Km Ferozpur Road, Lahore
	Brand Name +Dosage Form + Strength	Epimate 50mg Tablet
	Composition	Each tablet contains:

		Topiramate…….50mg
	Diary No. Date of R& I & fee	26381, 28-12-2017, 20,000/- 28-12-2017
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Topiramate Teva 50mg tablets MHRA Approved
	Me-too status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP status	GMP inspection dated 19-10-2017 shows satisfactory level of compliance.
	Remarks of the Evaluator [XIV].	Upon query, the firm has replied that there was a typographic error at one place and correct dosage form is tablet instead of capsule.
	Decision: Approved.	
1718.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals (Pvt.) Ltd, 8th Km Thokar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tcosmid 10mg Injection
	Composition	Each ml contains: Lacosamide…….10mg
	Diary No. Date of R& I & fee	26646, 29-12-2017, 20,000/- 29-12-2017
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 20ml; Rs. 364.71/- per pack
	Approval status of product in Reference Regulatory Authorities.	Lacosamide G.L. Pharma GmbH 10 mg/ml solution for infusion (MHRA Approved)
	Me-too status	Lacosbar 200mg/20ml Injection by Barrett Hodgson
	GMP status	Last inspection report dated 25/03/2019, satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIV].	The firm has provided Liquid injectable (vial & Ampoule) section.
	Decision: Approved with innovator's specifications.	

b. Deferred cases

1719.	Name and address of manufacturer / Applicant	M/s Searle IV Solutions Pvt Ltd., 1.5 km, Manga Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Macovir Tablet 200/50mg
	Composition	Each Film coated tablet contains: Lopinavir…….200mg Ritonavir…….50mg
	Diary No. Date of R& I & fee	Dy.No. 8771 dated 23/04/2020,Rs. 20,000/- 23-04-2020
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved.
	Me-too status	Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED (Reg No. 62250)
	GMP status	The firm has been granted GMP Certificate based on inspection issued on 15-03-2018.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of evidence of approval of

		applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee (M-295).
	Evaluation by PEC	The firm has submitted revised Form-5 with film coating composition as per reference formulation.
	Decision: Deferred for submission of fee for revision of formulation.	
1720.	Name and address of manufacturer / Applicant	M/s Elite Pharma (Pvt.) Ltd, 9.5KM., Sheikhupura Road, P.D.H. Street, Lahore.
	Brand Name +Dosage Form + Strength	Lincomin Injection
	Composition	Each 2ml contains: Lincomycin as Hydrochloride……...600mg
	Diary No. Date of R& I & fee	3697 dated 19-03-2011, Rs. 8000/-, 20-11-2013, 12000/- (photocopy attached)
	Pharmacological Group	Lincosamide
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	1 × 2ml ampoule ; Rs. 40/- 5 × 2ml ampoule ; Rs. 250/-
	Approval status of product in Reference Regulatory Authorities.	Lincomycin Injection 600mg/2ml ampoule (TGA approved).
	Me-too status	Olinc 600mg/2ml vial of M/s Bosch (Reg#025416)
	GMP status	• GMP inspection dated 16-07-2018 concluded that the panel of inspectors is of the opinion that the firm was maintaining satisfactory level of GMP compliance as per Drugs Act, 1976 and rules framed thereunder.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for provision of followings: (M-256) • Fee Challan of Rs. 12,000. • Clarification for assay limit of stated amount is not as per BP in some pages. • Manufacturing Method. • Copy of official monograph. • Commitment as per 251st meeting. • Last inspection report. • Proof of FTIR and Thin layer chromatography. • Gas chromatography along with flame ionization detector required as per analysis method provided by the firm. Registration Board referred the case to QA & LT Division for updated GMP status of the firm (M-293).
	Evaluation by PEC	• The firm has claimed BP specifications. • The firm has referred to inspection report dated 11-02-2015 which confirm presence of FTIR, TOC analyzer and Liquid particle counter. • GMP inspection dated 16-07-2018 concluded that the panel of inspectors is of the opinion that the firm was maintaining satisfactory level of GMP compliance as per Drugs Act, 1976 and rules framed thereunder. • The firm has submitted Form-5 with correct salt form alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1932735) dated 25-09-2019. • QA Division vide letter No.F.4-34/98-QA (Vol-I) informed that the panel was of the opinion that *the firm may be allowed to resume production in Liquid*

		Injectable Ampoule and Semi Solid (Cream/ Ointment) Sections only.
	Decision: Approved.	
1721.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Laboratories. 14-km, Adyala Road, Rawalpindi
	Brand Name +Dosage Form + Strength	Procyl Tablets
	Composition	Each Tablet Contains: Piroxicam Beta Cyclodextrin eq. to piroxicam.....20mg
	Diary No. Date of R& I & fee	Dy.No 4172, 02-02-2018, Rs. 20,000/-, 02-02-2018
	Pharmacological Group	Oxicams
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	BREXIN 20 mg scored tablet by Pierre Fabre Medicament (ANSM Approved)
	Me-too status	Brexin Tablets 20mg by Chiesi (Reg#10637)
	GMP status	Inspection report 21-12-2017 The panel unanimously recommended for the renewal of DML.
	Previous remarks of the Evaluator.	The label claim is not as per Reference product.
	Previous decision(s)	Deferred for revision of formulation and label claim as per the reference regulatory authority approved reference product (M-288).
	Evaluation by PEC	The firm has revised label claim as per reference formulation alongwith fee challan of Rs. 5000/- (deposit slip # 2049365) dated 18-08-2020.
	Decision: Approved with innovator's specifications.	
1722.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Azitabin 500mg capsules
	Composition	Each capsule contains: Azithromycin (as dihydrate)……..500mg
	Diary No. Date of R& I & fee	Dy. No.3813; 08-06-2015; Rs.20,000/- (08-06-2015)
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 × 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Zygrel 500mg capsules of M/s Searle Pakistan Pvt. Ltd.
	GMP status	Last inspection report dated 02-01-2017 confirms good compliance to GMP.
	Previous remarks of the Evaluator.	**Shortcomings** Evidence of approval of applied formulation in referencel regulatory authorities/agencies Product specific outline of method of manufacturing (method of manufacturing for Tiotropium bromide capsules is provided instead of azithromycin capsules).
	Previous decision(s)	Deferred for following: **(M-274)** Evidence of approval of applied formulation in reference regulatory authorities/agencies. Product specific outline of method of manufacturing. Deferred for following: Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting (M-291).

	Evaluation by PEC	The firm has revised dosage form from capsule to tablet dosage form due to non-availability of capsule in RRA. Each film coated tablet contains: Azithromycin as dihydrate……500mg Fee challan of PKR 5000/- (deposit slip#1996362) dated 10-06-2020 has been submitted.
	Decision: Deferred for submission of differential fee of Rs. 15,000/- for revision of dosage form and also confirmation for non-registration of new formulation.	
1723.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fude Tablets
	Composition	Each film coated tablet contains: Sodium Fusidate……250 mg
	Diary No. Date of R& I & fee	976 dated 16-04-2015, Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	As per SRO/ 2x10's
	Approval status of product in Reference Regulatory Authorities.	Fucidin 250mg Tablets of MHRA approved
	Me-too status	Pandate 250mg Tablets of M/s Panacea Pharma
	GMP status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above, it may be concluded that M/s Linta Pharmaceuticals is operating at an acceptable level of GMP standard.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of installation and operational qualification of Potentiometer by the area FID (M-249).
	Evaluation by PEC	The firm has submitted copy of purchase invoice for potentiometer.
	Decision: Deferred for confirmation of installation and operational qualification of Potentiometer.	
1724.	Name and address of manufacturer / Applicant	M/s. Lisko Pakistan, L-10-D, Block No 21, Shaheed Rashid Minhas Road, FB Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fluco Tablet 150mg
	Composition	Each tablet contains: Fluconazole……150mg
	Diary No. Date of R& I & fee	676, 25-04-2016, Rs. 20,000/- (25-04-2016)
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diflucan (50mg, 150mg) hard capsules by M/s Pfizer Limited, MHRA Approved.
	Me-too status	Diflucan 150mg Cap by M/s Pfizer, Reg. No. 11828
	GMP status	The firm
	Previous remarks of the Evaluator.	The application(s) was evaluated and it has been found that it is incomplete in respect of following deficiencies/shortcomings: 1. Composition and manufacturing outline not provided. 2. Undertaking of Form 5 not signed. 3. Specify the dosage form whether film coated or uncoated tablets. The firm has replied the deficiencies and changed the dosage form from Tablet to Capsule.

		Each Capsule contains: Fluconazole…….150mg
	Previous decision(s)	Deferred for the submission of fresh fee for revised dosage form (M-274).
	Evaluation by PEC	The firm has submitted copy of fee challan of Rs. 20,000/- (deposit slip # 0545433) dated 20-12-2017 for revision of dosage form.
	Decision: Approved with following label claim: **Each capsule contains:** **Fluconazole……150mg**	
1725.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Acromax Ointment 0.1%
	Composition	Each gram of ointment contains: - Tacrolimus as monohydrate……..1mg
	Diary No. Date of R& I & fee	Dy. No.1410, Dated 31-10-14,Rs. 20,000
	Pharmacological Group	Immunomodulator/Macrolide
	Type of Form	Form 5
	Finished product Specification	As per Innovator Specs.
	Pack size & Demanded Price	Rs. 950/30g tube, Rs. 800/10g tube, Rs. 300/5g tube, Polycoated collapsible tube
	Approval status of product in Reference Regulatory Authorities.	Protopic 0.1% ointment by Leo Laboratories Limited (MHRA Approved)
	Me-too status	Eczemas Ointment of Brookes Pharmaceuticals
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for the decision regarding requirement of manufacturing facility for tacrolimus (M-269).
	Evaluation by PEC	Registration Board decided to grant registration of these products in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Registration Board decided to approve registration of applied product in general manufacturing area with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1726.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Acromax Ointment 0.03%
	Composition	Each gram of ointment contains:- Tacrolimus as monohydrate……..0.3mg
	Diary No. Date of R& I & fee	Dy. No.1409, Dated 31-10-14, Rs. 20,000
	Pharmacological Group	Immunomodulator/Macrolide
	Type of Form	Form 5
	Finished product Specification	As per Innovator Specs.
	Pack size & Demanded Price	Rs. 950/30g tube, Rs. 800/10g tube, Rs. 300/5g tube, Polycoated collapsible tube
	Approval status of product in Reference Regulatory Authorities.	Protopic 0.03% ointment by M/s LEO Pharma A/S, MHRA Approved.
	Me-too status	Imunol Ointment 0.03% by M/s Saffron Pharma (Pvt) Ltd, (Reg # 046443)
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•

	Previous decision(s)	Deferred for the decision regarding requirement of manufacturing facility for tacrolimus (M-269).
	Evaluation by PEC	Registration Board decided to grant registration of these products in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Registration Board decided to approve registration of applied product in general manufacturing area with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1727	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Endocor 100 injection
	Composition	Each ampoule / 1ml contains Octreotide as acetate……..100mcg
	Diary No. Date of R& I & fee	Dy. 764; 02-09-2016; Rs.20,000/- (01-09-2016)
	Pharmacological Group	Somatostatin Analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1x5 ampoule Rs.2533.90
	Approval status of product in Reference Regulatory Authorities.	Sandostatin, (USFDA Approved)
	Me-too status	Sandostatin Injection by M/s Novartis Pharma. (Reg#013472)
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board referred to Biological Drugs Division, being biological drug (M-263). Subsequently registration referred the formulation of Octreotide acetate injection to the PE & R Division for further processing (M-277). Registration Board deferred the case for following observations/clarifications: (M-282). Manufacturing requirement with respect to atmospheric conditions i.e. temperature, for applied formulation. Source of API whether of synthetic or biological origin.
	Evaluation by PEC	Deputy Director Biological Drugs, has forwarded this application vide letter No. F.3-158/2017 AD (BE&R) dated 16-02-2018, with request to process the case as per above decision of Registration Board. The firm has submitted that the API Octreotide Acetate is synthetic by its origin and processes and is not a biological product. Accordingly, COA of API manufacturer M/s Bachem Americas, Inc. 3132 Kashiwa Street Torranc, CA 90505, USA has been submitted which indicates API as of synthetic origin.
	Decision: Registration Board deferred for further deliberation to review innovator's product status whether biological or synthetic origin.	
1728	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Endocor 50 injection
	Composition	Each ampoule / 1ml contains Octreotide as acetate …..50mcg

	Diary No. Date of R& I & fee	Dy. 757 02-09-2016; Rs.20,000/- (01-09-2016)
	Pharmacological Group	Somatostatin Analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1x5 ampoule Rs.1333.90
	Approval status of product in Reference Regulatory Authorities.	Sandostatin, (USFDA Approved)
	Me-too status	Octreotide 50mcg injection by m/s m/s. Revive health care, (Reg#082066)
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board referred to Biological Drugs Division, being biological drug (M-263). Subsequently registration referred the formulation of Octreotide acetate injection to the PE & R Division for further processing (M-277). Registration Board deferred the case for following observations/clarifications: (M-282). Manufacturing requirement with respect to atmospheric conditions i.e. temperature, for applied formulation. Source of API whether of synthetic or biological origin.
	Evaluation by PEC	Deputy Director Biological Drugs, has forwarded this application vide letter No. F.3-158/2017 AD (BE&R) dated 16-02-2018, with request to process the case as per above decision of Registration Board. The firm has submitted that the API Octreotide Acetate is synthetic by its origin and processs and is not a biological product. Accordingly, COA of API manufacturer M/s Bachem Americas, Inc. 3132 Kashiwa Street Torranc, CA 90505, USA has been submitted which indicates API as of synthetic origin.
	Decision: Registration Board deferred for further deliberation to review innovator's product status whether biological or synthetic origin.	
1729.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Prolone Injection
	Composition	Each 2ml contains: Methylprednisolone acetate …….40mg
	Diary No. Date of R& I & fee	Dy.No.763 dated 02-09-2016, Rs.20,000/-
	Pharmacological Group	Glucocorticoid
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1x2ml, Rs.224.62/-
	Approval status of product in Reference Regulatory Authorities.	Depo-medrol by Pfizer Pharma (EU)/USA,
	Me-too status	Depo-medrol by Pfizer Pharma,
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board deferred products and advised to get approval from Licensing Division for lyophilized injection vials (steroids) and liquid injection ampoules (steroids) respectively for further processing by Registration Board (M-273).
	Evaluation by PEC	The firm has submitted that the said product can be be

		manufactured in the approved *Liquid Injection Hormone section* with justification that Methyprednisolone on the basis of pharmacological classification is a synthetic steroid which falls under the sub-heading of hormones.
	Decision: Deferred for confirmation of required manufacturing facility i.e., Liquid Injectable Steroid section for applied formulation.	
1730.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Bpride Tablets
	Composition	Each tablet contains:- Cinitapride as Hydrogen Tartrate……1mg
	Diary No. Date of R& I & fee	Dy.No.1959 dated 27-03-2015, Rs.8000/- (Photocopy attached) Rs.12,000/- 25-03-2015
	Pharmacological Group	Gastroprokinetic Agent
	Type of Form	Form-5
	Finished product Specification	----
	Pack size & Demanded Price	10's, Rs. 170
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg uncoated tablet by Almirall, SA (Spain Approved)
	Me-too status	Cidine Tablets 1mg by M/s Highnoon Lab
	GMP status	17-08-2016 recommended for the grant of additional sections
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for the submission of GMP inspection report conducted within the last 01 year (M-277).
	Evaluation by PEC	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Decision: Approved with innovator's specifications.	
1731.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Renon-25 Tablets
	Composition	Each tablet contains:- Eplerenone …….. 25mg
	Diary No. Date of R& I & fee	Dy No. 550, dated 4-06-2014, Rs.20,000
	Pharmacological Group	Aldosterone Blocker
	Type of Form	Form-5
	Finished product Specification	Innovator Specs
	Pack size & Demanded Price	1x14's; Rs. 478/pack
	Approval status of product in Reference Regulatory Authorities.	Inspra by GD Searle LLC (USFDA Approved)
	Me-too status	Urenon 25mg Tablet by Tabros.
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board deferred the case for the confirmation of steroidal tablet section (M-269).
	Evaluation by PEC	The firm was granted additional section as "Tablet hormone section" vide panel inspection dated 17-08-2016.
	Decision: Deferred for confirmation of approved manufacturing facility for steroidal tablet section.	
1732.	Name and address of manufacturer / Applicant	M/s. Shaigan Pharmaceuticals,14 Km,Adyala Road, Post Office Dahgal, Rawalpindi
	Brand Name +Dosage Form + Strength	Renon-50 Tablets
	Composition	Each tablet contains:- Eplerenone …….. 50mg
	Diary No. Date of R& I & fee	Dy No. 386, dated 04-06-2014, Rs.20,000

	Pharmacological Group	Aldosterone Blocker
	Type of Form	Form-5
	Finished product Specification	Innovator Specs
	Pack size & Demanded Price	1x14's; Rs. 832/pack
	Approval status of product in Reference Regulatory Authorities.	Inspra by GD Searle LLC (USFDA Approved)
	Me-too status	Urenon 50mg Tablet by Tabros.
	GMP status	Panel inspection dated 25-09-2019 recommended the renewal of DML.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board deferred the case for the confirmation of steroidal tablet section (M-269).
	Evaluation by PEC	The firm was granted additional section as "Tablet hormone section" vide panel inspection dated 17-08-2016.
	Decision: Deferred for confirmation of approved manufacturing facility for steroidal tablet section.	
1733.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products (Pvt.) Ltd, D-122, S.I.T.E, Karachi
	Brand Name +Dosage Form + Strength	Zolot-S 75/75mg Tablet
	Composition	Each film coated tablet contains: Clopidogrel as Hydrogen Phosphate…….75mg Aspirin…….75mg
	Diary No. Date of R& I & fee	Dy. No: 1065 dated 30.04.2011, Rs.8,000/-, 26.07.2013, Rs.12,000/-
	Pharmacological Group	Antiplatelet
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 14.50/Tablet; 10's
	Approval status of product in Reference Regulatory Authorities.	COPLAVIX 75 mg/75 mg clopidogrel (as hydrogen sulfate)/aspirin tablets blister pack by M/s anofi-Aventis Australia Pty Ltd (TGA Approved)
	Me-too status	CoPlavix Tablets 75/75mg by M/s Sanofi (Reg#075978)
	GMP status	GMP inspection conducted on 01-10-2018 concluded that the firm is found to be complying at a good level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for verification of bi-layered compression machine by area FID (M-258). Registration board deferred the case for further deliberation since the product approved by reference regulatory authorities is film coated tablet prepared by mixing granules of clopidogrel (prepared by wet granulation) and aspirin (prepared by dry granulation) (M-286).
	Evaluation by PEC	Area FID in his inspection report dated 01-10-2018 confirmed that the firm had double-pressing automatically revolving piece-pressing machine (Rotary tablet press ZP420-31D). The firm has submitted that the applied formulation is in line with reference product which is film coated in TGA i.e., APO-CLOPIDOGREL 75/75. Moreover, verification of bi-layered machine has been confirmed from Area FID inspection report.
	Decision: Deferred for confirmation of method of manufacture of applied formulation in the light of innovator product.	

1734.	Name and address of manufacturer / Applicant	M/s Opal Laboratories (Pvt.) Limited, LC-41, L.I.T.E., Landhi, Karachi
	Brand Name +Dosage Form + Strength	GALVO TABLET 50mg
	Composition	Each film coated tablet contains: Vildagliptin……..….50mg
	Diary No. Date of R& I & fee	14492, 18-04-2018, 20,000/-, 18-04-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2 × 14's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Galvus 50mg tablet of M/s Novartis Pharmaceuticals, UK Ltd (MHRA Approved)
	Me-too status	Galvus 50mg tablet of M/s Novartis Pharmaceuticals, Karachi (Reg # 059038)
	GMP status	The firm has submitted copy of inspection conducted on 08-02-2018 in which the firm was considered to be operating at fair level of compliance.
	Previous remarks of the Evaluator.	• Reference formulation approved in MHRA is uncoated tablet while applied formulation is film coated tablet. Revision of Form-5 and master formulation with requisite fee is required.
	Previous decision(s)	Deferred for revision of formulation as per reference / innovator product (M-290).
	Evaluation by PEC	The firm has submitted revised master formulation with following label claim: Each tablet contains: Vildagliptin……..50mg Fee challan of Rs. 5000/- (Deposit slip # 1926745) dated 24 -08-2020 has been submitted.
	Decision: Approved with innovator's specifications and with following label claim: **Each tablet contains:** **Vildagliptin…….50mg**	
1735.	Name and address of manufacturer / Applicant	M/s Alfalah Pharma Pvt Ltd., 12 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Milton 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….....500mg
	Diary No. Date of R& I & fee	12248 dated 02/06/2020 Rs. 20,000/- dated 02-06-2020
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	6's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azic 500mg Tablet by M/s Nabi Qasim (Reg # 055584)
	GMP status	Panel inspection dated 26-06-2019 & 16-09-2019 recommnended renewal of DML and grant of additional section i.e., Capsule General
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of application on approved format of Form-5 and GMP status (M-295).
	Evaluation by PEC	The firm has submitted application on Form-5 and updated GMP status.
	Decision: Approved.	
1736.	Name and address of manufacturer / Applicant	M/s Alfalah Pharma Pvt Ltd., 12 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azolike 250mg Capsule

	Composition	Each Capsule Contains: Azithromycin as Dihydrate….....250mg
	Diary No. Date of R& I & fee	12250 dated 02/06/2020 Rs. 20,000/- dated 02-06-2020
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	6's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zidor Capsule 250mg of M/s Winthrox Karachi. (Reg.# 074943)
	GMP status	Panel inspection dated 26-06-2019 & 16-09-2019 recommnended renewal of DML and grant of additional section i.e., Capsule General
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of application on approved format of Form-5 and GMP status (M-295).
	Evaluation by PEC	The firm has submitted application on Form-5 and updated GMP status.
	Decision: Approved.	
1737.	Name and address of manufacturer / Applicant	M/s Alfalah Pharma Pvt Ltd., 12 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azolike 500mg Capsule
	Composition	Each Capsule Contains: Azithromycin as Dihydrate….....500mg
	Diary No. Date of R& I & fee	12249 dated 02/06/2020 Rs. 20,000/- dated 02-06-2020
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	6's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Azithromycin 500mg Capsules Uni pharma (Pvt) Ltd., Lahore. 071422
	GMP status	Panel inspection dated 26-06-2019 & 16-09-2019 recommnended renewal of DML and grant of additional section i.e., Capsule General
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting (M-295).
	Evaluation by PEC	The firm has submitted application on Form-5 and updated GMP status.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 278th meeting.	
1738.	Name and address of manufacturer / Applicant	M/s Albert Pharmaceuticals (Pvt.) Ltd., Plot # 127, Sundar Industrial Estate, Raiwind, Lahore
	Brand Name +Dosage Form + Strength	DELOAD Dry Suspension
	Composition	Each 5ml (when reconstituted) contains: Nitazoxanide……100mg
	Diary No. Date of R& I & fee	19412, 30-10-2017, 20,000/-, 23-10-2017
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	30ml & 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alinia by Romark (USFDA Approved)

	Me-too status	Diatazox 100mg/5ml Dry Suspension of M/s S.J & G
	GMP status	GMP status could not be verified.
	Previous remarks of the Evaluator.	The firm has provided oral dry powder suspension (General) section.
	Previous decision(s)	Registration Board referred the case to QA & LT Division for updated GMP status of the firm (M-290).
	Evaluation by PEC	The firm has submitted copy of GMP certificate granted based on inspection dated 30-05-2019.
	Decision: Approved with innovator's specifications.	
1739.	Name and address of manufacturer / Applicant	M/s Albert Pharmaceutical (Pvt)Ltd. Plot # 127 Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cipralt Dry Suspension 250mg/5ml
	Composition	Each 5ml (when reconstituted) contains: Ciprofloxacin (as hydrochloride monohydrate) …250mg
	Diary No. Date of R& I & fee	DiaryNo:8420; 11/07/2017; Rs:20,000/-
	Pharmacological Group	Anti-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60 ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA Ciproxin® 250 mg/5 ml granules and solvent for oral Suspension by M/s Bayer Healthcare, (MHRA approved)
	Me-too status	Novidat dry powder suspension 250mg/5ml by Sami Pharma
	GMP status	New DML
	Previous remarks of the Evaluator.	In reference agencies it is approved as ciprofloxacin "granules for oral suspension while the firm has applied for powder for oral suspension. Solvent Soya lecithin, Medium chain triglycerides, Strawberry flavor, Sucrose, Purified water.
	Previous decision(s)	Deferred for the following reasons (M-274): Clarification of dosage form as the applicant has applied for "powder for oral suspension" which is different from the product approved in reference agenciesi.e. "granules for oral suspension" Clarification of type of solvent supplied by manufacturer for reconstitution of applied formulation, as solvent approved in reference agencies is an oil based solvent consisting of following ingredients that are "Soya lecithin, Medium chain triglycerides, Strawberry flavor, Sucrose, Purified water".
	Evaluation by PEC	The firm has revised label claim with ciprofloxacin base as follows alongwith submission of fee: Each 5ml suspension (when reconstituted) contains: Ciprofloxacin as taste masked granules……250mg The firm has clarified dosage form as granules for oral suspension. Source of granules: M/s Vision Pharmaceuticals The firm has submitted copy of GMP certificate granted based on inspection dated 30-05-2019.
	Decision: Deferred for submission of fee for revision of formulation as per reference.	
1740.	Name and address of manufacturer / Applicant	M/s Albert Pharmaceutical (Pvt) Ltd. Plot # 127 Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cipralt Dry Suspension 125mg/5ml
	Composition	Each 5ml (when reconstituted) contains:

		Ciprofloxacin (as hydrochloride monohydrate) …….125mg
	Diary No. Date of R& I & fee	Diary No:8421; 11/07/2017; Rs:20,000/-
	Pharmacological Group	Anti-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60 ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro 125mg/5ml of Bayer Healthcare,(USFDA)
	Me-too status	Ciprin 125mg/5ml suspension of M/s Werrick pharmaceuticals
	GMP status	New DML
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for deliberation in light of 269th Registration Board meeting and GMP (M-274).
	Evaluation by PEC	The firm has revised label claim with ciprofloxacin base as follows alongwith submission of fee: Each 5ml suspension (when reconstituted) contains: Ciprofloxacin as taste masked granules……125mg The firm has clarified dosage form as granules for oral suspension. Source of granules: M/s Vision Pharmaceuticals The firm has submitted copy of GMP certificate granted based on inspection dated 30-05-2019.
	Decision: Deferred for submission of fee for revision of formulation as per reference.	
1741.	Name and address of manufacturer / Applicant	M/s Albert Pharmaceutical (Pvt) Ltd. Plot # 127 Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Klaret Dry Suspension125mg/5ml
	Composition	Each 5ml (when reconstituted) contains: Clarithromycin (as granules)……125mg
	Diary No. Date of R& I & fee	Diary No: 8423; 11/07/2017; Rs:20,000/-
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml/As perSRO
	Approval status of product in Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5mlbyM/s Abbvie, (USFDA Approved).
	Me-too status	Klarim Dry Suspension 125mg/5ml of Amrose Pharmaceuticals
	GMP status	New DML
	Previous remarks of the Evaluator.	Firm has applied for powder for oral suspension while in reference agencies it is approved as granules for oral suspension.
	Previous decision(s)	Deferred for clarification of dosage form as the applicant has applied for "powder for oral suspension" which is different from the product approved in reference agenciesi.e. "granules for oral suspension" (M-274).
	Evaluation by PEC	The firm has clarified dosage form as granules for oral suspension. Source of granules: M/s Vision Pharmaceuticals The firm has submitted copy of GMP certificate granted based on inspection dated 30-05-2019.
	Decision: Approved.	
1742.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec (Pvt) Limited, Karachi
	Brand Name +Dosage Form + Strength	L SULPRID Tablet 25mg
	Composition	Each film coated tablet contains:

		Levosulpiride……..25mg
	Diary No. Date of R& I & fee	Dy. No: 2290-R-II dated 31-12-10, 8000/- dated 31-12-10, 12000 dated 01-08-13
	Pharmacological Group	Benzamide antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC/ 2x10's
	Approval status of product in Reference Regulatory Authorities.	Levopraid 25 mg tablet of AIFA Italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	GMP inspection dated 25-09-2019 overall GMP compliance is rated as GOOD.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation (M-248).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in AIFA Italy.
	Decision: Approved with innovator's specifications.	
1743	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec (Pvt) Limited, Karachi
	Brand Name +Dosage Form + Strength	L SULPRID Tablet 50mg
	Composition	Each film coated tablet contains: Levosulpiride……..50mg
	Diary No. Date of R& I & fee	Dy. No: 2289-R-II dated 31-12-10, 8000/- dated 31-12-10, 12000 dated 01-08-13
	Pharmacological Group	Benzamide antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC/ 2x10's
	Approval status of product in Reference Regulatory Authorities.	Levopraid 50 mg tablet of AIFA Italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	GMP inspection dated 25-09-2019 overall GMP compliance is rated as GOOD.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation (M-248).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in AIFA Italy.
	Decision: Approved with innovator's specifications.	
1744	Name and address of manufacturer / Applicant	**Applicant:** M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore **Manufacturer:** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Opizole 40mg Injection
	Composition	Each vial contains:- Omeprazole Sodium (Lyophilized) eq. to Omeprazole…….40mg
	Diary No. Date of R& I & fee	Dy No. 3061, 14-05-2013, Rs.50000/-, 14-05-2013
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV 40mg Injection of sandoz (TGA)
	Me-too status	Risek 40mg injection by Getz Pharma
	GMP status	GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018.

	Previous remarks of the Evaluator.	
	Previous decision(s)	The Board deferred the case for clarification regarding name of the firm (M-265). Deferred for submission of GMP status of "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)" and number of products already approved in contract manufacturing and details of section approved by CLB (M-289).
	Evaluation by PEC	Secretary RB apprised the Board that firm has changed their name to M/s A'raf Pharmaceuticals Lahore. The firm has submitted documents of licensing division dated 11th November, 2013 for change of name of company to "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)". The firm M/s A'raf (Pvt) Ltd submitted copy of panel inspection dated 12-06-2020 wherein the panel concluded that the firm has good compliance to GMP. M/s A'raf (Pvt) Ltd, Lahore has no products on contract manufacturing. The firm M/s English Pharmaceutical Industries, Lahore has provided Dry powder Injectable (General) section for the manufacturing of this formulation.
	Decision: Approved with innovator's specifications.	
1745.	Name and address of manufacturer / Applicant	**Applicant:** M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore **Manufacturer:** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Piprazo 4.50gm Injection
	Composition	Each vial contains:- Sterile Piperacillin Sodium eq. to Piperacillin ……4.0gm Sterile Tazobactam Sodium eq. to Tazobactam ……0.50gm
	Diary No. Date of R& I & fee	Dy No. 3062, 14-05-2013, Rs.50000/-, 14-05-2013
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin Tazobactum by Sandoz (MHRA Approved)
	Me-too status	Tazocin 4.5gm by Wyeth Ltd
	GMP status	GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018.
	Previous remarks of the Evaluator.	
	Previous decision(s)	The Board deferred the case for clarification regarding name of the firm (M-265). Deferred for submission of GMP status of "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)" and number of products already approved in contract manufacturing and details of section approved by CLB (M-289).
	Evaluation by PEC	Secretary RB apprised the Board that firm has changed their name to M/s A'raf Pharmaceuticals Lahore. The firm has submitted documents of licensing division dated 11th November, 2013 for change of name of company to "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)".

		The firm M/s A'raf (Pvt) Ltd submitted copy of panel inspection dated 12-06-2020 wherein the panel concluded that the firm has good compliance to GMP. M/s A'raf (Pvt) Ltd, Lahore has no products on contract manufacturing. The firm has provided Dry Powder Injectable (Penicillin) section.
	Decision: Approved with innovator's specifications.	
1746.	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/80mg
	Composition	Each tablet contains: Amlodipine (as besylate)……5mg Telmisartan……..…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5454 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 5mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 5/80 Tablet by M/s Pharmevo (Reg#073762)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Previous remarks of the Evaluator.	In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. Firm has not submitted evidence of double layer compression machine.
	Previous decision(s)	Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine (M-288).
	Evaluation by PEC	The firm has submitted evidence of procurement of multiple layer compression machine with following details; Copy of invoice of multiple layered compression machine attached. Copy of delivery challan is attached
	Decision: Deferred for submission of Installation Qualification (IQ), Operational Qualification, Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet bilayered machine.	
1747.	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/40mg
	Composition	Each tablet contains: Amlodipine (as besylate)……5mg Telmisartan……..…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5453 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	14's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 5mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 5/40 Tablet by M/s Pharmevo (Reg#073763)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Previous remarks of the Evaluator.	In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. Firm has not submitted evidence of double layer compression machine.
	Previous decision(s)	Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine (M-288).
	Evaluation by PEC[XIV]	The firm has submitted evidence of procurement of multiple layer compression machine with following details; Copy of invoice of multiple layered compression machine attached. Copy of delivery challan is attached.
	Decision: Deferred for submission of Installation Qualification (IQ), Operational Qualification, Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet bilayered machine.	
1748.	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 10/80mg
	Composition	Each tablet contains: Amlodipine (as besylate)……10mg Telmisartan……..…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5455 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Pharmacological Group	Angiotensin II antagonists and calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 10mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 10/80 Tablet by M/s Pharmevo (Reg#073763)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Previous remarks of the Evaluator.	In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. Firm has not submitted evidence of double layer compression machine.
	Previous decision(s)	Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine (M-288).

	Evaluation by PEC[XIV]	The firm has submitted evidence of procurement of multiple layer compression machine with following details; Copy of invoice of multiple layered compression machine attached. Copy of delivery challan is attached.
	Decision: Deferred for submission of Installation Qualification (IQ), Operational Qualification, Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet bilayered machine.	
1749.	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Stinough 150mg Capsule
	Composition	Each capsule contains: Erdosteine……..…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5438 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2 × 10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Erdozet Capsules 150mg by M/s S.J&G (Reg#073809)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Previous remarks of the Evaluator.	Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) alongwith registration number, brand name and name of firm (M-288).
	Evaluation by PEC[XIV]	The firm has submitted me-too reference "Erdos 150mg Capsule of Platinum Pharmaceuticals (Reg#053047)". However, evidence of Approval status of product in Reference Regulatory Authorities could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration board in 275th meeting.	
1750.	Name and address of manufacturer / Applicant	M /s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-industrial triangle kahuta road Islamabad.
	Brand Name +Dosage Form + Strength	FAVIRULZ Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Favipiravir……..……200mg
	Diary No. Date of R& I & fee	Dy.No. 13274 dated 10/06/2020 Rs. 50,000/- dated 10-06-2020
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10's, 20's, 30's, 40's/ As per DPC
	Approval status of product in Reference Regulatory Authorities.	Avigan 200mg Film coated Tablet by M/s Toyama Chemical Co., Ltd Japan (PMDA Approved)
	Me-too status	N/A
	GMP status	The firm has been granted GMP certificate based on inspection conducted on 18/03/2019.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of application on Form-5D (M-

		295).
	Evaluation by PEC	The firm has submitted application on Form-5D alongwith undertaking to perform stability studies before marketing of the product.
	Decision: Approved.	
1751.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	EVAGAN Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Favipiravir…..……200mg
	Diary No. Date of R& I & fee	Dy.No. 13133 dated 09/06/2020 Rs. 20,000/- dated 09-06-2020
	Pharmacological Group	Antiviral
	Type of Form	Form-5D
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	Avigan 200mg Film coated Tablet by M/s Toyama Chemical Co., Ltd Japan (PMDA Approved)
	Me-too status	N/A
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Previous remarks of the Evaluator.	Differential fee of Rs. 30,000/- alongwith Form-5D is required to be
	Previous decision(s)	Deferred for submission of differential fee of Rs. 30,000/- alongwith application on Form-5D (M-295)
	Evaluation by PEC	The firm has submitted differential fee of PKR 30,000/- (deposit slip # 2026070) dated 12-06-2020.
	Decision: Approved.	
1752.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Valet 50mg Tablet
	Composition	"Each Film coated tablet Contains: Voriconazole…50mg"
	Diary No. Date of R& I & fee	Dy.No 40933 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Japanese Pharmacopoeia Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA as film coated Tablet
	Me-too status	Vorinaz 50mg Tablet of Atco Lab. Karachi
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section (General) 4. Liquid Syrup (General)
	Previous remarks of the Evaluator.	Please submit either evidence of reference product approved as uncoated tablet or otherwise convert it to film coated tablet alongwith submission of requisite fee.
	Previous decision(s)	Deferred for submission of either evidence of reference product approved as uncoated tablet or otherwise change it to film coated tablet alongwith submission of requisite

		fee, master formulation & manufacturing method.
	Evaluation by PEC	The firm has submitted revised Form-5 with Film coating composition and label claim as per reference formulation alongwith submission of fee challan of Rs. 5000/- (deposit slip # 2003835) dated 17-08-2020.
	Decision: Approved.	
1753.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Valet 200mg Tablet
	Composition	"Each Film coated Tablet Contains: Voriconazole…200mg"
	Diary No. Date of R& I & fee	Dy.No 40934 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Japanese Pharmacopoeia Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA as film coated Tablet
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup (General)
	Previous remarks of the Evaluator.	Please submit either evidence of reference product approved as uncoated tablet or otherwise convert it to film coated tablet alongwith submission of requisite fee.
	Previous decision(s)	Deferred for submission of either evidence of reference product approved as uncoated tablet or otherwise change it to film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.
	Evaluation by PEC	The firm has submitted revised Form-5 with Film coating composition and label claim as per reference formulation alongwith submission of fee challan of Rs. 5000/- (deposit slip # 2003834) dated 17-08-2020.
	Decision: Approved.	
1754.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Itrazole 100mg Capsule
	Composition	"Each Capsule Contains: Itraconazole (as IR pellets)……100mg"
	Diary No. Date of R& I & fee	Dy.No 40905 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	4's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the

		firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Previous remarks of the Evaluator.	COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Previous decision(s)	Deferred for submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions (M-295).
	Evaluation by PEC	The firm has submitted COA, GMP certificate and stability study data of pellets from M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad.
	Decision: Approved with innovator's specifications.	
1755.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Diclowin 75mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac sodium…75mg"
	Diary No. Date of R& I & fee	Dy.No 40928 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	20's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Voltaren 75mg delayed release tablet discontinued in USFDA not due to safety or efficacy reasons.
	Me-too status	Fedgesic Tablets 75mg of Fedro Pharmaceutical
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation as enteric coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Previous decision(s)	Deferred for evidence of approval of applied formulation as enteric coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (M-295).
	Evaluation by PEC	Approval status of applied formulation is confirmed in USFDA.
	Decision: Approved.	
1756.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Albawin 200mg Tablet

	Composition	"Each Chewable Tablet Contains: Albendazole……200mg"
	Diary No. Date of R& I & fee	Dy.No 40924 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	2"s, 10"s: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Not verifiable
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Previous remarks of the Evaluator.	Evidence of applied formulation/drug i.e. Albendazole 200mg chewable tablet already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. □ Please submit justification for carrying out film coating of a chewable tablet.
	Previous decision(s)	Deferred for the following: (M-295) • Evidence of applied formulation/drug i.e. Albendazole 200mg chewable tablet already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	The firm has submitted me-too reference of "Albendol 200mg Tablet of M/s Vision Pharma (Reg # 038418)" which has been verified.
	Decision: Approved.	
1757.	Name and address of manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form + Strength	Loret 5mg/5ml Syrup
	Composition	"Each 5ml Contains: Loratadine……5mg"
	Diary No. Date of R& I & fee	Dy.No 40914 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (as solution)(amber glass bottle)
	Me-too status	Loradine Syrup 5mg/5ml of Global Pharmaceuticals
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General)

		4. Liquid Syrup(General)
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for the following: • Mention type of primary packaging material of applied formulation. • Submit clarification regarding physical form of applied drug product as reference product is approved as solution while applied formulation is syrup.
	Evaluation by PEC	The firm has submitted approval status of syrup dosage form in MHRA as follows: "LORATADINE 5MG/5ML SYRUP of Galpharm Healthcare Limited Hugh House Dodworth Business Park Barnsley South Yorkshire" Primary packaging material: Amber glass bottle
	Decision: Approved.	
1758.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	O-Lanz Plus Capsules 6/25mg
	Composition	Each hard gelatin capsule contains: Olanzapine …….....6mg Fluoxetine hydrochloride eq. to Fluoxetine……25mg
	Diary No. Date of R& I & fee	Dy. No.2997 ; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Symbyax of M/s Eli Lilly & Company (USFDA Approved)
	Me-too status	Co-Depricap of M/s Nabiqasim
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has informed that current GMP status of the firm shall be considered as compliant.
	Decision: Approved.	
1759.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	O-Lanz Plus Capsules 12/25mg
	Composition	Each hard gelatin capsule contains: Olanzapine …….....12mg Fluoxetine hydrochloride eq. to Fluoxetine……25mg
	Diary No. Date of R& I & fee	Dy. No.2998 ; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Symbyax of M/s Eli Lilly & Company (USFDA Approved)
	Me-too status	Co-Depricap of M/s Nabiqasim
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board referred the case to QA & LT

		Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has informed that current GMP status of the firm shall be considered as compliant.
	Decision: Approved.	
1760.	Name and address of manufacturer / Applicant	M/s Sigma Pharma International (Pvt.) Ltd.,Plot # E-50, North Western industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	SOMTIME CAPSULE
	Composition	Each Capsule contains: Tamsulosin Hydrochloride (modified release pellets)…….0.4mg Source of pellets: RA Chem pharma, India
	Diary No. Date of R& I & fee	14774, 20-04-2018, 100,000/-, 09-04-2018
	Pharmacological Group	Alpha1 adrenoceptor Blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 × 10's ; As per DRAP policy 1 × 20's ; As per DRAP policy 1 × 30's ; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	FLOMAX RELIEF MR of Boehinger Ingelheim, UK (MHRA)
	Me-too status	Tamsolin 0.4mg of M/s GETZ Pharma (Reg#050392)
	GMP status	GMP inspection dated 18-09-2018 concluded that the firm was at satisfactory level of GMP Compliance.
	Previous remarks of the Evaluator.	• Dosage form mentioned on Form-5 is film coated tablet while brand name suggests capsule dosage form. Clarification/Revision is required. • Label claim of applied formulation is not correctly mentioned. Revision of Form-5 with correct label claim along with requisite fee is required to be submitted.
	Previous decision(s)	Deferred for revision of formulation as per reference product alongwith applicable fee (M-290). Deferred for submission of differential fee of Rs. 15,000/- for revision of dosage form (M-293).
	Evaluation by PEC	The firm has revised label from film coated to capsule in label claim with submission of fee challan of 5000/- (deposit slip # 1915883) dated 13-09-2019. The firm has submitted fee challan of Rs. 15,000/- (deposit slip # 1915919) dated 06-03-2020. The firm is granted GMP certificate based on inspection dated 19-10-2019.
	Decision: Approved with innovator's specifications.	
1761.	Name and address of manufacturer / Applicant	M/s Sigma Pharma International Pvt. Limited E-50, N.W.I.Z., Port Qasim Karachi
	Brand Name +Dosage Form + Strength	Citrosalt 4gm Sachet
	Composition	Each Sachet contains:- Sodium Bicarbonate……1.76gm Sodium Citrate Anhydrous…….0.63gm Citric Acid Anhydrous…….0.72gm Tartaric Acid…….0.89gm
	Diary No. Date of R& I & fee	17-11-2014 (217), Rs. 20,000/-
	Pharmacological Group	Antacids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Packs 20's & 100's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	CITRO SODA Sachet of Abbott Lab
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes that on the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of formulation approval in stringent regulatory agencies (M-246). Deferred for revision of formulation as per reference product (M-293).
	Evaluation by PEC	The firm has revised the strength of sachet as per me-too reference which is approved by Registration Board in 289th meeting after correction in composition. Each 4gm of Sachet contains:- Sodium Bicarbonate……1.716gm Sodium Citrate Anhydrous…….0.613gm Citric Acid Anhydrous…….0.702gm Tartaric Acid…….0.858gm **Me-too composition:** Citrosoda Regular Each 4gm of sachet contains:- Sodium Bicarbonate …….1.716gm Sodium Citrate…….....0.613gm Citric Acid…....0.702gm Tartaric Acid……0.858gm The firm has submitted fee challan of PKR. 20,000/- (deposit slip # 1915920) dated 06-03-2020 for revision of formulation. The firm is granted GMP certificate based on inspection dated 19-10-2019.
	Decision: Approved with innovator's specifications and change of brand name.	
1762.	Name and address of manufacturer / Applicant	M/s Sigma Pharma International Pvt. Limited E-50, N.W.I.Z., Port Qasim Karachi
	Brand Name +Dosage Form + Strength	Sofnac SR Tablet 100mg
	Composition	Each film coated sustained release tablet contains: Diclofenac Sodium……..100mg
	Diary No. Date of R& I & fee	Dy. No. 202, 01-02-2017, Rs.20,000/- (7-01-2017)
	Pharmacological Group	Non-steroidal anti-inflammatory agent (NSAID)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dicloflex Retard 100 mg prolonged release tablet by M/s Dexcel Pharma Ltd. M**HRA** approved
	Me-too status	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes that on the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of formulation approval in reference stringent regulatory agencies (M-246). Deferred for submission of fee of Rs. 5000/- for revision of master formulation (M-293).

	Evaluation by PEC	Approval status of applied formulation has been verified in MHRA. The firm has submitted revised master formulation with hypromellose as sustained release ingredient. The firm has submitted fee of PKR. 5000/- (deposit slip # 1915921) dated 06-03-2020 for revision of formulation. The firm is granted GMP certificate based on inspection dated 19-10-2019.
	Decision: Approved.	
1763.	Deleted due to Duplication in agenda	
1764.	Name and address of manufacturer / Applicant	M/s Vega Pharmaceuticals (pvt.) Ltd, Lahore
	Brand Name +Dosage Form + Strength	Clarith 250mg Tablets
	Composition	Each film coated tablet contains: Clarithromycin……..250mg
	Diary No. Date of R& I & fee	Dated 29.04.2013 Rs. 20,000/- (photocopy)
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 350/10's
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250 mg Film-coated Tablets. MHRA approved
	Me-too status	Clarital 250mg Tablet.(Reg. No. 85501)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for the submission of following (M-261) i. Inspection report ii. Commitment as per decision of board iii. Finished product specification are incomplete. iv. Fee Rs. 8000/- and 12000/- is Photocopy v. Approval status in reference countries and Pakistan
	Evaluation by PEC	The firm has submitted copy of inspection report dated 09-01-2019 & 21-03-2019 concludes that the firm is operating at fair level of compliance. The firm has claimed USP specifications and submitted commitments as per 251st meeting of Registration Board.
	Decision: Approved.	
1765.	Name and address of manufacturer / Applicant	M/s Wilson's pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	WILBOG TABLETS 50mg
	Composition	Each film coated tablet contains: Eltrombopag Olamine eq. to Eltrombopag free acid……..50mg
	Diary No. Date of R& I & fee	14581, 19-04-2018, 20,000/-, 19-04-2018
	Pharmacological Group	Thrombopoietin Receptor Agonist
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	25's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROMACTA Tablet of Novartis Pharms , (USFDA approved)
	Me-too status	Revolade Tablet 50mg of GSK, Karachi (Reg#069585)
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Previous remarks of the Evaluator.	

	Previous decision(s)	Deferred for clarification of pharmacological group of applied formulation (M-290).
	Evaluation by PEC	The firm has submitted that Eltrombopag Olamine belongs to pharmacological group of thrombopoietin receptor agonists as per FDA reference product.
	Decision: Approved with innovator's specifications.	
1766.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals, 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Simax 0.4mg Capsule
	Composition	Each capsule contains: Tamsulosin Hydrochloride as SR pellets……..…0.4 mg
	Diary No. Date of R& I & fee	Dy.No 13083 dated 09-04-2018 Rs.20,000/- Dated 09-04-2018
	Pharmacological Group	Alpha1 Adrenoceptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 2x10's/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flomax 0.4mg capsule by M/s Boehringer Ingelheim Pharmaceuticals (USFDA Approved)
	Me-too status	M-Sol 0.4mg Capsule of M/s Regal Pharma (Reg.#081977)
	GMP status	16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section, to M/s Siam Pharmaceuticals Islamabad
	Previous remarks of the Evaluator.	• Source of pellets not submitted by the firm.
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-290).
	Evaluation by PEC	The firm has submitted following: Source of pellets: M/s Vision Pharmaceuticals The firm has submitted revised label claim as per reference alongwith submission of fee of Rs. 5000/- (Deposit slip # 2040588) dated 28-08-2020.
	Decision: Approved.	
1767.	Name and address of manufacturer / Applicant	M/s Bosch Pharmacetuicals (Pvt) Ltd. (Plant-II), Plot No. 209, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ultraquin Plus Cream
	Composition	Each gm contains: Hydroquinone……...4 % w/w Fluocinolone Acetonide……0.01 % w/w Tretinoin……....0.05 % w/w
	Diary No. Date of R& I & fee	Dy. No.471; 29-03-2016; Rs.20,000/- (28-03-2016)
	Pharmacological Group	Depigmenting agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's x 15gm; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Hydrocin Cream of M/s Fynk Pharmaceuticals (Reg.# 081262)
	GMP status	Last GMP Inspection dated 7-9-2016 with conclusive remarks of Acceptable level of cGMP compliance.
	Previous remarks of the Evaluator.	Latest inspection report conducted within one year shall be submitted.

	Previous decision(s)	Deferred for submission of latest inspection report conducted within one year by DRAP (M-274).
	Evaluation by PEC	The firm has submitted copy of inspection report dated 05-11-2019 concludes that the firm was considered to be operating at an acceptable of compliance with GMP guidelines.
	Decision: Deferred for clarification of pharmacological group for applied formulation.	
1768.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals, Plot # 7, Street# S-6, National Industrial Zone, Rawat
	Brand Name +Dosage Form + Strength	FERDOX TABLETS 20mg
	Composition	Each film coated tablet contains Piroxicam (as beta cyclodextrin)……20 mg
	Diary No. Date of R& I & fee	Rs. 20,000/- vide Dy. No. 1943 dated 05-11-2015
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's / as per price fixed by Government
	Approval status of product in Reference Regulatory Authorities.	Cycladol tablet (ANSM approved)
	Me-too status	Pirujin Tablet M/s Jupiter Pharma
	GMP status	GMP inspection report dated 02-10-2019 is complying satisfactory level of cGMP as of today.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for clarification as firm claimed their formulation as film coated tablet while innovator's brand is uncoated tablet (M-255).
	Evaluation by PEC	The firm has revised master formulation with uncoated composition alongwith fee challan of Rs. 5000/- (deposit slip # 2044499) dated 25-08-2020.
	Decision: Approved with innovator's specifications.	
1769.	Name and address of manufacturer / Applicant	**Applicant:** M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; **Contract manufacturer:** M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	SEC 40mg IV Injection
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9513: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm M/s Honig Pharmaceuticals was inspected on 11.10.2018 and reported complying GMP.
	Previous remarks of the Evaluator.	• The shelf-life of the product in TGA is 18 months. • The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned.

		• The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Previous decision(s)	Deferred for the following: (M-289) • Adjustment of weight of API as per salt factor is required in Master Formula. • Clarify whether the product is filled and lyophilized or only lyophilized powder is filled. • Clarify the dosage form.
	Evaluation by PEC	The firm has submitted calculation of API as per Salt factor. Regarding method of manufacturing, the firm submitted that we will fill "Ready to fill Lyophilized Powder" in sterile vials under aseptic sterile conditions and microbiologically controlled environment. Moreover, the firm stated that mistakenly the term injection was mentioned in the Form-5 of the product and the correct dosage form is Lyophilized Powder for Injection. However, fee of such revision is not submitted.
	Decision: Deferred for submission of fee for revision of dosage form.	
1770.	Name and address of manufacturer / Applicant	**Applicant:** M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; **Contract manufacturer:** M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxing 400mg/250ml IV Injection
	Composition	Each 250 ml contains: Moxifloxacin as hydrochloride……400mg
	Diary No. Date of R& I & fee	Dy No. 9512: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	(250ml) 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. TGA approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm M/s Honig Pharmaceuticals was inspected on 11.10.2018 and reported complying GMP.

	Previous remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm mentioned HDPE as primary packaging. Then changed to LDPE). The reference product is packed in Glass Type I clear bottle. • The firm was asked for adjustment of weight of API as per salt factor. The firm did not revised the same. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer.
	Previous decision(s)	Deferred for clarification about the packaging (M-289)
	Evaluation by PEC	The firm has submitted that mistakenly the packaging material mentioned as LDPE in Form-5 of the product dossier. However, we will use Packaging material as Clear Glass bottles of USP Type-I. However, fee of such revision is not submitted.
	Decision: Deferred for submission of fee for revision of dosage form.	
1771	Name and address of manufacturer / Applicant	**Applicant:** M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; **Contract manufacturer:** M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Xamp 40mg IV Injection
	Composition	Each vial contains: Esomeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9511: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm M/s Honig Pharmaceuticals was inspected on 11.10.2018 and reported complying GMP.
	Previous remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection.

		• The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned 33% potency of lyophilized powder, but did not clarify the other 67% composition. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Previous decision(s)	Deferred for the following: (M-289) • Adjustment of weight of API as per salt factor is required in Master Formula. • Clarification whether the product is filled and lyophilized or only lyophilized powder is filled. • Clarification of the dosage form. • Clarification about the composition of the dosage form (powder).
	Evaluation by PEC	The firm has submitted calculation of API as per Salt factor. Regarding method of manufacturing, the firm submitted that we will fill "Ready to fill Lyophilized Powder" in sterile vials under aseptic sterile conditions and microbiologically controlled environment. Moreover, the firm stated that mistakenly the term injection was mentioned in the Form-5 of the product and the correct dosage form is Lyophilized Powder for Injection. However, fee of such revision is not submitted.
	Decision: Deferred for submission of fee for revision of dosage form.	
1772.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, Pvt limited, 14 Km, Adayala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zevast Tablet 10mg/10mg
	Composition	Each film-coated tablet contains: Ezetimibe …….10mg Simvastatin……..10mg
	Diary No. Date of R& I & fee	Dy. No.3589 ; 27-12-2016; Rs.20,000/- (22-12-2016)
	Pharmacological Group	Cholesterol Absorption Inhibitor/HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	1 × 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Simbex tablet 10/10 of Searle Pharma
	GMP status	Last GMP inspection was conducted on 14-12-2017 and the report concludes issuance of GMP certificate for export purpose.
	Previous remarks of the Evaluator.	Non-pharmacopoeial as is not present in B.P. & U.S.P. The drug is applied as film-coated while it is approved in USFDA, MHRA, Netherland, Australia & France as uncoated.
	Previous decision(s)	Deferred for clarification of applied formulation since reference product is approved as uncoated tablet whereas firm has applied for film coated tablet.(M-278) Deferred for submission for revision of formulation (M-283).
	Evaluation by PEC	The firm has submitted revised Form-5 where the finished product is uncoated tablet in line with reference country as follows

		Each tablet contains: Ezetimibe …….10mg Simvastatin……..10mg The firm has submitted fee challan of PKR 5000/- (deposit slip 2038084) dated 02-09-2020.
	Decision: Approved with innovator's specifications.	
1773.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, Pvt limited, 14 Km, Adayala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zevast Tablet 10mg/20mg
	Composition	Each film-coated tablet contains: Ezetimibe …….10mg Simvastatin……..20mg
	Diary No. Date of R& I & fee	Dy. No.3551 ; 22-12-2016; Rs.20,000/- (22-12-2016)
	Pharmacological Group	Cholesterol Absorption Inhibitor/HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	1 × 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Simbex tablet 10/20 of Searle Pharma
	GMP status	Last GMP inspection was conducted on 14-12-2017 and the report concludes issuance of GMP certificate for export purpose.
	Previous remarks of the Evaluator.	Non-pharmacopoeial as is not present in B.P. & U.S.P. The drug is applied as film-coated while it is approved in USFDA, MHRA, Netherland, Australia & France as uncoated.
	Previous decision(s)	Deferred for clarification of applied formulation since reference product is approved as uncoated tablet whereas firm has applied for film coated tablet.(M-278) Deferred for submission for revision of formulation (M-283).
	Evaluation by PEC	The firm has submitted revised Form-5 where the finished product is uncoated tablet in line with reference country as follows Each tablet contains: Ezetimibe …….10mg Simvastatin……..20mg The firm has submitted fee challan of PKR 5000/- (deposit slip 2038085) dated 02-09-2020.
	Decision: Approved with innovator's specifications.	
1774.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, Pvt limited, 14 Km, Adayala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zevast Tablet 10mg/40mg
	Composition	Each film-coated tablet contains: Ezetimibe …….10mg Simvastatin……..40mg
	Diary No. Date of R& I & fee	Dy. No.3543 ; 27-12-2016; Rs.20,000/- (22-12-2016)
	Pharmacological Group	Cholesterol Absorption Inhibitor/HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	1 × 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Simbex tablet 10/40 of Searle Pharma

	GMP status	Last GMP inspection was conducted on 14-12-2017 and the report concludes issuance of GMP certificate for export purpose.
	Previous remarks of the Evaluator.	Non-pharmacopoeial as is not present in B.P. & U.S.P. The drug is applied as film-coated while it is approved in USFDA, MHRA, Netherland, Australia & France as uncoated.
	Previous decision(s)	Deferred for clarification of applied formulation since reference product is approved as uncoated tablet whereas firm has applied for film coated tablet.(M-278) Deferred for submission for revision of formulation (M-283).
	Evaluation by PEC	The firm has submitted revised Form-5 where the finished product is uncoated tablet in line with reference country as follows Each tablet contains: Ezetimibe …….10mg Simvastatin……..40mg The firm has submitted fee challan of PKR 5000/- (deposit slip 2038086) dated 02-09-2020.
	Decision: Approved with innovator's specifications.	
1775.	Name and address of manufacturer / Applicant	M/s. Legacy Pharmaceuticals (Pvt) Ltd, 111-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Ribena-FF Tablets
	Composition	Each chewable tablet contains:- Iron polymaltose complex equivalent to elemental iron …….100mg Folic Acid……..0.75mg
	Diary No. Date of R& I & fee	21-1-2010, Dy No. 46, Rs.8000, Rs.12000, 4-8-2015
	Pharmacological Group	Antianaemic
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	10's/ Rs.120.00
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Ferrum FA of M/s PharmEvo
	GMP status	Inspection date 18/07/2019. The Panel recommended renewal of DML.
	Previous remarks of the Evaluator.	Firm has claimed mfg. specs and the product is not present in available versions of USP & BP.
	Previous decision(s)	Deferred for clarification of dosage form as firm has applied for chewable tablet whereas manufacturing method states Film coating also (M-267).
	Evaluation by PEC	The firm has submitted clarification that our product is uncoated and chewable tablet but due to typing mistake master formulation included coating materials. Revised master formula for chewable tablet is submitted by the firm.
	Decision: Approved with innovator's specifications.	
1776.	Name and address of manufacturer / Applicant	M/s. Welwink Pharmaceuticals, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Olexa 10 mg Tablet
	Composition	Each tablet contains: Escitalopram as Oxalate…….....10 mg
	Diary No. Date of R& I & fee	Dy. No. 4309; 13-03-2017; Rs.20,000/- (13-03-2017)
	Pharmacological Group	Antipsychotic/ Selective serotonin reuptake inhibitors (SSRI)

	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	10's & 14's / As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CIPRALEX 10mg **film-coated** tablets by M/s H.Lundbeck (MHRA approved)
	Me-too status	Citanew 10 mg Tablet by Hilton, (Reg. # 036426).
	GMP status	Last GMP inspection was conducted on 20-12-2017 and the report concludes : "Firm was operating at satisfactory level of GMP compliance for all sections except Liquid Injectable section for which the firm was advised to provide Liquid Particle counter and TOC at earliest."
	Previous remarks of the Evaluator.	• Addition of Methylene chloride in master formulation needs justification.
	Previous decision(s)	Deferred for change of composition for film coating since methylene chloride is banned excipient (M-279). Deferred for submission of fee for revision of formulation (M-285).
	Evaluation by PEC	The firm has submitted revised Form-5 for film coating composition without methylene chloride and with following label claim as below: Each Film coated tablet contains: Escitalopram as Oxalate…….....10 mg The firm has submitted fee challan of Rs. 5000/- (deposit slip # 1909921) dated 31-12-2019.
	Decision: Approved.	
1777.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Phase-1, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Baxtran Syrup 5ml
	Composition	Each 5ml contains Sulfamethoxazole…..…200mg Trimethoprim……..…40mg
	Diary No. Date of R& I & fee	Dy. No.325, R&I Dated 18.12.2014, Rs. 20,000
	Pharmacological Group	Macrolides, Anti-infective.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & Rs.40/-
	Approval status of product in Reference Regulatory Authorities.	Trimethoprim+Sulphamethoxazole 40+200mg By Teva , USFDA
	Me-too status	Not available
	GMP status	Last GMP Inspection 05.04.2017 concludes acceptable level of GMP compliance.
	Previous remarks of the Evaluator.	Me-too couldn't be confirmed.
	Previous decision(s)	Deferred for evidence of me-too in the same dosage form and strength (M-270).
	Evaluation by PEC	000384: Septran Paediatric suspension of GSK The submitted me-too and international availability is of suspension whereas the applied formulation is syrup.
	Decision: Deferred for evidence of applied formulation in syrup dosage form in reference regulatory authorities.	
1778.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals, A-1/A, Phase-1, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Dinar Dry suspension 250mg
	Composition	Each 5ml suspension contains Cephradine ……250mg
	Diary No. Date of R& I & fee	Dy. No.317, R&I Dated 18.12.2014, Rs. 20,000
	Pharmacological Group	1st generation cephalosporin antibiotic

	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	120ml x1's & Rs.230/=
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cephradine 250mg suspension by Aries
	GMP status	Last GMP Inspection 05.04.2017 concludes acceptable level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for verification of the manufacturing facility (M-270).
	Evaluation by PEC	The firm has provided Dry Powder Suspension (Cephalosporin) section as evidence from licensing letter vide letter No.F.2-14/2007-Lic dated 25th Feb, 2011.
	Decision: Approved.	
1779.	Name and address of manufacturer / Applicant	"M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi"
	Brand Name +Dosage Form + Strength	Osvir dry suspension 12mg/ml
	Composition	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…..…..12mg
	Diary No. Date of R& I & fee	Dy.No. 9453 dated 30/04/2020 Rs. 20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tamiflu 12mg/ml for Suspension (oseltamivir as phosphate) by M/s Roche, Italy AIFA Approved.
	Me-too status	Ozenta 12mg Dry Suspensin by M/s Hilton, reg. No. 42219
	GMP status	GMP inspection dated 24-07-2018, current GMP compliance is rated as Good.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for the following: (M-295) • Clarification since the attached fee challan is for Amaquin (50mg/5ml). • Submission of evidence of approval of applied formulation as "Syrup" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.
	Evaluation by PEC	The firm has submitted that erroneaously fee challan of Amaquin 50mg /5ml was compiled with the dossier instead of Osvir Dry Suspension. Correct copy of fee challan of Osvir Dry Suspension is enclosed. The firm has further stated that in the registration dossier, we applied for Dry suspension as per reference formulation. Copy of submitted Form-5 is enclosed.
	Decision: Approved.	
1780.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited 32- Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Comfyl Syrup
	Composition	Each 5 ml contains: Acefylline Piperazine……..….45 mg Diphenhydramine hydrochloride……..8 mg

	Diary No. Date of R& I & fee	Fast Track, 10-05-13, Rs. 60,000/-, 10-05-13
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	120 ml Rs. 50/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Acefyl cough Syrup by Nabiqasim
	GMP status	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation by review committee (M-242).
	Evaluation by PEC	The firm has submitted that DRAP has already granted registration of same formulation to many pharmaceutical companies, some brands are mentioned below for your reference: Acefyl cough syrup of M/s Nabiqasim (Reg#023394) Cefyl ESF Syrup of M/s Epla labs (Reg#024432) Cosome DA syrup of M/s Martin Dow (Reg#075906) Ebrantil EXP syrup of M/s Akhai (Reg#053002) In the light of above, we would request you to grant us registration.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 278th meeting	
1781	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan (pvt) Ltd. A-115, SITE, Karachi.
	Brand Name +Dosage Form + Strength	Win-Spa 40mg/2ml IM/IV Injectable
	Composition	Each 2ml contains: Drotaverine HCl…….40mg
	Diary No. Date of R& I & fee	Dy. No: 1619 dated, 24.09.2012 Rs.20,000/-
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Hi-Spa 40mg/2ml Injection of M/s Helix
	GMP status	Inspection report dated 19/07/2019 which concludes that GMP compliance level is rated as good.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of approval status by reference regulatory authorities (M-258).
	Evaluation by PEC	The approval status of applied formulation has been confirmed by three European countries Bulgaria**,** Romania**,** Hungary.
	Decision: Approved with innovator's specifcations.	
1782	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	CINPRO Dry suspension 125mg/5ml
	Composition	Each 5ml Contains:- Ciprofloxacin base taste masked pellets 25% eq. to Ciprofloxacin…….125mg
	Diary No. Date of R& I & fee	Dy No.2055 dated 19-03-15, Rs. 20,000/-
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5

	Finished product Specification	Manufacturer
	Pack size & Demanded Price	As Per SRO/ Pack of 60ml
	Approval status of product in Reference Regulatory Authorities.	Cipro 125mg/5ml of Bayer Healthcare,(USFDA)
	Me-too status	Novidat 125mg/5ml of Sami Pharmaceuticals
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation (M-249).
	Evaluation by PEC	The firm has revised dosage form from suspension to Dry powder suspension alongwith submission of fee of PKR 20,000/- (deposit slip # 1926356) dated 12-08-2020.
	Decision: Approved with USP specifications. Diluent should be as per innovator.	
1783.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	CINPRO Dry suspension 250mg/5ml
	Composition	Each 5ml Contains:- Ciprofloxacin base taste masked pellets 25% eq. to Ciprofloxacin…….250mg
	Diary No. Date of R& I & fee	Dy No.2055 dated 19-03-15, Rs. 20,000/-
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	As Per SRO/ Pack of 60ml
	Approval status of product in Reference Regulatory Authorities.	Ciproxin® 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved
	Me-too status	Novidat 250 mg/5ml of Sami Pharmaceuticals
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation (M-249).
	Evaluation by PEC	The firm has revised dosage form from suspension to Dry powder suspension alongwith submission of fee of PKR 20,000/- (deposit slip # 1926357) dated 12-08-2020.
	Decision: Approved with USP specifications. Diluent should be as per innovator.	
1784.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Syrup
	Composition	Each 5ml contains:- Carbocysteine……...100mg
	Diary No. Date of R& I & fee	Dy No. 547, 03-02-2015; PKR 20,000/-, 03-02-2015
	Pharmacological Group	Mucolytic agent
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	120ml, as per brand leader
	Approval status of product in Reference Regulatory Authorities.	BRONCATHIOL CHILDREN, oral solution of MELISANA Pharma (ANSM approved)
	Me-too status	Rhinathiol Syrup by Sanofi
	GMP status	The firm has been granted GMP certificate based on inspection dated 30-04-2019.
	Previous remarks of the Evaluator.	

	Previous decision(s)	Deferred for following (M-269). Change of brand name as the same is registered for different active ingredient Latest GMP inspection report conducted within 1 year Evidence of approval by reference regulatory authorities approved by Registration Board in 249th meeting Clarification regarding the submitted innovator's specification as it was already declared that this product is not registered in any reference regulatory authority
	Evaluation by PEC	The firm has submitted following: We will change the brand name of the said applied formulation. GMP certificate submitted. Approval status of applied formulation in ANSM has been verified. Reference formulation is in oral solution while applied formulation is syrup.
	Decision: Approved with change of brand name.	
1785.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Plus Syrup
	Composition	Each 5ml contains:- Carbocysteine…….100mg Promethazine hydrochloride….2.5mg
	Diary No. Date of R& I & fee	Dy No. 542, 03-02-2015; PKR 20,000/-, 03-02-2015
	Pharmacological Group	Mucolytic agent ; Antihistamine
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	120ml, as per brand leader
	Approval status of product in Reference Regulatory Authorities.	BRONCATHIOL Promethazine Syrup of MELISANA Pharma (ANSM approved)
	Me-too status	Rhinathiol Syrup by Sanofi
	GMP status	The firm has been granted GMP certificate based on inspection dated 30-04-2019.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following (M-269). Change of brand name as the same is registered for different active ingredient Latest GMP inspection report conducted within 1 year Evidence of approval by reference regulatory authorities approved by Registration Board in 249th meeting Clarification regarding the submitted innovator's specification as it was already declared that this product is not registered in any reference regulatory authority
	Evaluation by PEC	The firm has submitted following: We will change the brand name of the said applied formulation. GMP certificate submitted. Approval status of applied formulation in ANSM has been verified.
	Decision: Approved with change of brand name.	
1786.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	AZOLOD Tablets 500mg
	Composition	Each film coated tablet contains:

		Azithromycin as Dihydrate……..500mg
	Diary No. Date of R& I & fee	Dy.No. 738, 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 20, 50,100, 250 and 500 tablets
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 500 mg Film-Coated Tablets by TEVA UK Limited (MHRA Approved)
	Me-too status	Zetro 500mg Tablet by Getz Pharma (Reg # 053120)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1787.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	IROP Syrup
	Composition	Each 15ml contains: Iron protein succinylate 800mg equivalent to elemental Iron……..40mg
	Diary No. Date of R& I & fee	Dy.No. 738, 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specs
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60,90, 120 and 450ml
	Approval status of product in Reference Regulatory Authorities.	Approved in Italy
	Me-too status	Wincuss Syrup 800mg/15 ml of Winthrox Karachi.
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.

	Evaluation by PEC	• The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1788.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	O-CIN Tablet 400mg
	Composition	Each film coated tablet contains: Ofloxacin……400mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Tarivid 400 of MHRA approved
	Me-too status	Clamocid 400mg Tablets by M/s Rock Pharmaceuticals Laboratories
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Diary No. is not mentioned. • The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1789.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	BISUB Tablet 265mg
	Composition	Each film coated tablet contains: Bismuth Subsalicylate……...265mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Mucosal protective
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the

		production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Evidence of approval of same generic, dosage form in reference agencies is not submitted. c. Applied drug is available locally as chewable tablet however firm has applied film coated. d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1790.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	BISUB Suspension
	Composition	Each 5ml contains: Bismuth subsalicylate…….….88mg
	Diary No. Date of R& I & fee	Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Anti-diarrhoeal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120, and 450ml
	Approval status of product in Reference Regulatory Authorities.	Pepti-Calm 525.6mg/30ml Oral Suspension of The Boots Company (MHRA approved)
	Me-too status	BISMOL Syrup of Macter International
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is required. b. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1791.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	K-ZIM Syrup 100mg/ 5ml
	Composition	Each 5ml contains: Cefixime as Trihydrate……....100mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Cephalosporin antibiotic

	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120, 450ml
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension by M/s Generics Ltd (MHRA Approved)
	Me-too status	Cefim Suspension 100mg/5ml by M/s Hilton Pharma (Reg#022108)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Master formulation of liquid oral dosage form is submitted. c. Precautions/controls submitted for liquid oral dosage form. d. Finished product specifications are not submitted. e. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Moreover, the status of the section for applied formulation is not clear from the report.
	Evaluation by PEC	• Reference formulation is Powder for oral suspension while applied formulation is syrup. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
1792.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYMOL Plus Tablet
	Composition	Each tablet contains: Paracetamol……...200mg Aspirin……..…300mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120, 450ml
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Liskoprin of Lisko Pvt Limited.
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not provided. b. Evidence of approval of same generic, dosage form and

		strength in reference drug agencies need to be submitted. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Approval status in reference agency is required to be submitted. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
1793.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYBION Capsules 50mg
	Composition	Each capsule contains: Diclofenac sodium enteric coated pellets (32%)……50mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Amfac Capsules of Ambrosia Pharma (Reg#056576)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted. c. Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted. d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Diary no. is missing • Source of Pellets: M/s Vision Pharma (Diclofenac sodium Enteric coated pellets 32%). • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1794.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYBION Capsules SR 100mg
	Composition	Each capsule contains: Diclofenac sodium SR pellets (32%)……..100mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Diclomax Retard 100mg modified release capsules of Galen Ltd., UK (MHRA approved)
	Me-too status	Flamex SR capsules 100mg of M/s Werrick Pharma (Reg#020592)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted. c. Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted. d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection
	Evaluation by PEC	• Source of Pellets: M/s Vision Pharma (Diclofenac sodium SR pellets 32%) • Diary no. is missing. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1795.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	C-PHOS Tablet 250mg
	Composition	Each film coated tablet contains: Chloroquine Phosphate ……...250mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Cloroquin 250mg Tablet of klifton Pharma (Reg#058332)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Formulation is approved in reference drug agencies as uncoated tablet however applied formulation is film

		coated. b. Reference of finished product spec need to be submitted as it is included in official pharmacopeia. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Diary no. is missing. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1796.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	GEMFLOX Tablet 320mg
	Composition	Each film coated tablet contains: Gemifloxacin as mesylate……..…..320mg
	Diary No. Date of R& I & fee	Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specs
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Factive Tablets of LG Life Sciences (USFDA approved)
	Me-too status	Gemixa Tablets of Bosch Pharma Karachi
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used as coating solvent which is class II as per ICH and its use has been restricted due to its inherent toxicity c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Diary no. is missing. • The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Deferred for verification of R & I details of applied formulation.	
1797.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	MOXILEX Tablet 400mg
	Composition	Each film coated tablet contains: Moxifloxacin as Hydrochloride……..400mg
	Diary No. Date of R& I & fee	Dy.No. 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specs
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's

	Approval status of product in Reference Regulatory Authorities.	Avelox of Bayer UK (MHRA approved)
	Me-too status	Avelox of Bayer Health Care Karachi
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used as coating solvent which is class II as per ICH and its use has been restricted due to its inherent toxicity c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection.
	Evaluation by PEC	• Diary no. is missing. • The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision: Approved with innovator's specifications. Reference shall be sent to budget and accounts for verification of fee challan.	

Case no. 02 Registration applications for local manufacturing of (Veterinary) drugs

a. New cases

1798	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	IMMUNE PLUS LIQUID
	Composition	Each liter contains: Vitamin E……200,000mg Sorbitol……50,000mg Choline Chloride…….50,000mg Propylene glycol……50,000mg Selenium…….150mg Zinc ……..4000mg
	Diary No. Date of R& I & fee	13290, 24-08-2017, 20,000/-, 24-08-2017
	Pharmacological Group	Vitamin and minerals
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 400ml, 500ml, 1000ml; Decontrolled
	Me-too status	DELTI IMMUNE of France
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug manufacturing license.
	Remarks of the Evaluator.	The submitted me-too reference could not be verified.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Rationale of using propylene glycol in formulation.**	

1799	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	BRO-MEN Liquid
	Composition	Each ml contains: Bromhexine hydrochloride……20mg Menthol……40mg
	Diary No. Date of R& I & fee	13289, 24-08-2017, 20,000/-, 24-08-2017
	Pharmacological Group	Expectorant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Litre, 2.5Litre, 5 Litre; Decontrolled
	Me-too status	BROMENT Oral Solution of M/s Baariq Pharma (Reg # 094458)
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug manufacturing license.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1800	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	INTERVAC DROP
	Composition	Each 1ml contains: Monobasic potassium phosphate…….0.37 mg Disodium phosphate dihydrate……0.72 mg Sodium chloride……..7.65 mg Disodium Edetate dihydrate……0.50 mg Methylene Blue……..0.17 mg
	Diary No. Date of R& I & fee	2522, 25-01-2017, 20,000/-, 25-01-2017
	Pharmacological Group	Vaccine diluent
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	Plastic bottles of 30ml, 36ml, 100ml; Decontrolled
	Me-too status	VACCI DROP Solvent of M/s Leads Pharma (Reg#046566)
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug manufacturing license.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications and change of brand name.	
1801	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	BLUE-VAC Granules
	Composition	Each gm contains: Sodium Thiosulphate…….100mg Patent Blue Color…….170mg
	Diary No. Date of R& I & fee	2521, 25-01-2017, 20,000/-, 25-01-2017
	Pharmacological Group	Blue Colouring Agent
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm; Decontrolled
	Me-too status	Not confirmed.
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug

		manufacturing license.
	Remarks of the Evaluator.	Me-too reference could not be verified.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Rationale of using Patent Blue color in formulation.**	
1802	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	CYPER POUR-ON SOLUTION
	Composition	Each ml contains: Cypermethrin…….100mg
	Diary No. Date of R& I & fee	13288, 24-08-2017, 20,000/-, 24-08-2017
	Pharmacological Group	Insecticide
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2000ml; Decontrolled
	Me-too status	CYPERMET Liquid of M/s Breeze Pharma (Reg#059165)
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug manufacturing license.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1803	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	TERMINATOR PLUS (Solution for Spray)
	Composition	Each litre contains: Glutaraldehyde....……..150gm Cocobenzyldimethylammonium chloride…..…100gm
	Diary No. Date of R& I & fee	Duplicate, 08-08-2016, 20,000/-, 08-08-2016
	Pharmacological Group	Broad Spectrum Disinfectant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	500ml, 1 litre, 2.5 litre, 5 litre, 10 litre, 25 litre, 50 litre; Decontrolled
	Me-too status	Terminator Solution by Bomac Laboratories (Newzealand)
	GMP status	After thorough evaluation of documents and inspection of the unit dated 28-02-2019 & 19-06-2019, the panel members decided to recommend the renewal of Drug manufacturing license.
	Remarks of the Evaluator.	Me-too reference of applied formulation could not be verified.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

b. Deferred cases (New section)

Registration Board deferred the cases of M/s Mylab Pvt. Ltd., Khankah Shariff, Bahawalpur for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.

The firm has submitted that we hereby state that we will manufacture non-steroidal hormone products in this newly approved section. We have also requested to Secretary Licensing Board to issue letter with respective change.

Liquid Injectable (Hormone) Section: (5molecules/12 products)

1804.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate……0.0042mg eq. to 0.004mg of Buserelin
	Diary No. Date of R& I & fee	40597, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Me-too status	CONCEPTAL INJECTION of M/s STAR LAB (Reg#058939)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	Follix Injection is mentioned on fee challan. Clarification is required.
	Previous Decision.	Deferred for following (M-289): Clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section. Clarification of applied product on fee challan
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1805.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate……0.0042mg eq. to 0.004 mg of Buserelin
	Diary No. Date of R& I & fee	40599, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml × 10's clear glass vial; Decontrolled
	Me-too status	CONCEPTAL INJECTION of M/s STAR LAB (Reg#058939)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1806.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate……0.0042mg eq. to 0.004mg of Buserelin
	Diary No. Date of R& I & fee	40600, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2.5ml × 10's clear glass vial; Decontrolled
	Me-too status	CONCEPTAL INJECTION of M/s STAR LAB (Reg#058939)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1807.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	FOLLIX INJECTION
	Composition	Each ml contains: Estradiol dipropionate……..1.00mg
	Diary No. Date of R& I & fee	40596, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml clear glass vial; Decontrolled
	Me-too status	Agofollin injection of Ghazi Brothers (Reg#028587)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1808.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	FOLLIX INJECTION
	Composition	Each ml contains: Estradiol dipropionate……..1.00mg
	Diary No. Date of R& I & fee	40594, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 5's clear glass vial; Decontrolled
	Me-too status	Agofollin injection of Ghazi Brothers (Reg#028587)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	

1809.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.075mg
	Diary No. Date of R& I & fee	40587, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 1's clear glass vial; Decontrolled
	Me-too status	Delmazine Injectable solution of M/s Prix Pharma[1]ceutica (Reg#018842)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e.,D-Cloprostenol…….0.075 mg per ml.
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	The firm has revised strength as per me-too reference and submitted fee challan of Rs. 20,000/- (deposit slip # 2053839) dated 01-09-2020.
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1810.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.075mg
	Diary No. Date of R& I & fee	40595, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 10's clear glass vial; Decontrolled
	Me-too status	Delmazine Injectable solution of M/s Prix Pharmaceutica (Reg#018842)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e.,D-Cloprostenol…….0.075 mg per ml.
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	The firm has submitted fee challan of Rs. 20,000/- (deposit slip # 2053840) dated 01-09-2020.
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1811.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.75mg
	Diary No. Date of R& I & fee	40593, 06-12-2018, 20,000/-, 04-12-2018

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	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 1's clear glass vial; Decontrolled
	Me-too status	Delmazine Injectable solution of M/s Prix Pharmaceutica (Reg#018842)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e., D-Cloprostenol……0.075 mg per ml.
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	
	Decision: Deferred for following: **Submission of fee of Rs. 20,000/- for revision of strength of applied formulation.** **Approval for non-steroidal hormone section from Licensing Division before issuance of Registration letter**	
1812.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40588, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic super analogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1813.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40588, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic superanalogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 5's clear glass vial; Decontrolled
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	

	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1814.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40591, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic superanalogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml × 5's clear glass vial; Decontrolled
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	
1815.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	STYROL INJECTION
	Composition	Each ml contains: Stilbestrol Dipropionate……10mg
	Diary No. Date of R& I & fee	40589, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Me-too status	BESTEROL Injection of M/s Selmore (Reg#071085)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	
	Previous Decision.	Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section
	Evaluation by PEC.	
	Decision: Approved with innovator's specifications. The Board further advised the firm to get approval of change of name for non-steroidal hormone section from Licensing Division before issuance of Registration letter.	

c. Deferred cases (Routine)

1816.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No. 27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Elkoflor Oral Solution
	Composition	Each ml contains: Florfenicol…….300mg

	Diary No. Date of R& I & fee	Dy.No 4474, 07-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	100ml, 250ml, 450ml, 500ml,1L,5L; Decontrolled
	Me-too status	N/A
	GMP status	MEDIFLOR 30% Oral Solution (Not confirmed)
	Previous remarks of the Evaluator.	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-288).
	Evaluation by PEC	Approval status of applied formulation has been verified in USFDA in injectable dosage form while applied formulation is in Oral solution.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
1817.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-Km, Adayala road, post office Dahga, Rawalpindi
	Brand Name +Dosage Form + Strength	Zixx liquid suspension 100ml
	Composition	Each Litre contains: Vitamin E acetate……...200,000mg Vitamin C (Ascorbic Acid)…….2000mg Sodium Selenite……...2200mg Zinc as sulphate……....10,000mg
	Diary No. Date of R& I & fee	Dy. No.925, R&I Dated 09-08-2016, Rs. 20,000/- (05.08.2016)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form -5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1x50ml, 1x100ml, 1x250ml, 1x500ml, 1x1000ml; Decontrolled
	Me-too status	Pam-E-Sel suspension of M/s Pameer Pharma
	GMP status	Inspection conducted on 26-10-2017 showed no observation as reported by QA.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. Registration Board directed the firm to submit details of target species for applied formulation (M-277). Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm (M-286).
	Evaluation by PEC	The firm has revised formulation as per me-too reference alongwith submission of fee of Rs. 20,000/- (deposit Slip # 1959373) dated 28-11-2019. Each Litre contains: Vitamin E acetate……..200,000mg Selenium (as sodium Selenite)……...2000mg Zinc as sulphate…….....9000mg Me-too reference : SEL-E Oral solution of M/s Noble Pharma (Reg # 063641) Zixx suspension is intended to be used in poultry.
	Decision: Rejected as firm has changed composition by removing one ingredient.	

1818.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt Ltd. 542-A & B, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Doxysin-C Powder
	Composition	Each gm Contains: Doxycycline Hyclate……500mg Tylosin Tartarate……100mg Colistin Sulfate…….30mg
	Diary No. Date of R& I & fee	Dy. No.284; 7-9-2015; Rs.20,000/- (7-9-2015)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 2.5kg, 5kg 10Kg, Decontrolled
	Me-too status	Doxy-Tol Powder by Lead Pharmaceuticals (Not Confirmed)
	GMP status	New Section Veterinary Powder (General & General Antibiotic)
	Previous remarks of the Evaluator.	Me-too status could not be confirmed.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-286). Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation (M-292).
	Evaluation by PEC	The firm has submitted Form-5 with revised strength of applied formulation as follows: Each gm contains: Doxycycline Hyclate……..…200mg Tylosin Tartarate……100mg Colistin Sulfate……..…30mg Me-too reference of "Doxi-Tol Powder of M/s. Leads pharma (Reg# 057053)" has been verified. Fee challan of Rs. 5000/- (Deposit slip#0792018) dated 06-08-2019 has been submitted. The firm has submitted differential fee of PKR 15000/- (deposit slip # 1998744) dated 14-01-2020.
	Decision: Approved with innovator's specifications.	
1819.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceutical, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Akacin 50 Injection
	Composition	Each 1ml contains:- Oxytetracycline hydrochloride……..50mg
	Diary No. Date of R& I & fee	Dy. No. 373 dated 8-10-2015, 20,000/-, 18-09-2015
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Santracycline -50 Injection of Sanna Labs (Reg#027419)
	GMP status	Copy of Panel inspection dated 09-11-2018 recommends renewal of DML except in oral powder penicillin section.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of composition of applied formulation whether quantity of API is in gm or mg (M-292). Deferred for submission of fee of Rs. 20,000/- for revision of formulation (M-293)

	Evaluation by PEC	The firm has provided liquid injectable (vial) section. The firm has submitted that we have applied quantity of API in mg as per me-too reference. It is a typographic error and written as grams therefore may be corrected accordingly. The firm has submitted fee challan of PKR 20,000/- (desposit slip # 1908602) dated 02-07-2020.
	Decision: Approved.	
1820.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica (Pvt) Ltd. Plot # 5 Pharmacity, 30-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Metaforce Injection
	Composition	Each 100ml injection contains:- L-carnitine HCl……613.3mg Thioctic Acid……20mg Pyridoxine HCl……..……..15mg Cyanocobalamine……..3.0mg D, L Acetylmethionine…….2000mg L-Arginine…….240mg L-Ornithine HCl……..……153.2mg L-Citrulline……..120.0mg L-Lysine HCl……..……..62.5mg Glycine…….150.0mg Taurine…….150.0mg Aspartic Acid……..150.0mg Glutamic Acid…….150.0mg Fructose……..5,000mg Sorbitol……..8,000mg
	Diary No. Date of R& I & fee	Dy. No.1132, 22-10-2012, Rs. 8000/-, 22-10-2012, Rs. 12000/-, 22-10-2012
	Pharmacological Group	Amino acids & sugar
	Type of Form	Form -5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml /Decontrolled
	Me-too status	Not confirmed
	GMP status	Panel inspection conducted on 16-12-2018 recommended for renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of me-too status (M-257).
	Evaluation by PEC	The firm has submitted me-too reference "Metabolase Injectable solution" of M/s Fatro Italy (Reg#019904) has been verified while composition was verified from marketed pack.
	Decision: Approved with innovator's specifications.	
1821.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Tetramide Spray
	Composition	Each 100gm Contains: Chlortetracycline……..367000IU Sulphanilamide……5.963mg
	Diary No. Date of R& I & fee	Dy.No 2024 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018
	Pharmacological Group	Insecticide/hormonal analogue
	Type of Form	Form-5
	Finished product Specification	In house
	Pack size & Demanded Price	210 ml; Decontrolled
	Me-too status	Orospray External Spray (Reg # 027453)

	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Previous remarks of the Evaluator.	• The firm has provided Aerosol vet section.
	Previous decision(s)	Deferred for clarification of manufacturing of powder formulation in aerosol section (M-288).
	Evaluation by PEC	The firm has submitted that finished product aerosol spray is not in powder form rather it is in liquid form. QC procedures are carried out by taking weight of contents of finished product because after filling liquid and propellant sealing is performed and after that container cannot be opened. Hence final filled volume is quantified by weight.
	Decision: Deferred for further deliberation regarding clarification of manufacturing of powder formulation in aerosol section.	
1822.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Roximax Topical Spray
	Composition	Each 170 gm Bottle Contains: Rifaximin…….0.5gm
	Diary No. Date of R& I & fee	Dy.No 2008 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	In house
	Pack size & Demanded Price	170gm; Decontrolled
	Me-too status	Fatroximin Topical Spray (Reg#021263)
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Previous remarks of the Evaluator.	• The firm has provided Aerosol vet section.
	Previous decision(s)	Deferred for clarification of manufacturing of powder formulation in aerosol section (M-288).
	Evaluation by PEC	The firm has submitted that finished product aerosol spray is not in powder form rather it is in liquid form. QC procedures are carried out by taking weight of contents of finished product because after filling liquid and propellant sealing is performed and after that container cannot be opened. Hence final filled volume is quantified by weight.
	Decision: Deferred for further deliberation regarding clarification of manufacturing of powder formulation in aerosol section.	
1823.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Anti-Mastitis Spray
	Composition	Each 15gm Contains: Rifaximin…….…….0.100gm Cefacetrile Sodium…..…0.200gm
	Diary No. Date of R& I & fee	Dy.No 2006, 16-01-2018 Rs. 20,000, 15-01-2018
	Pharmacological Group	Anti-Mastitis
	Type of Form	Form-5
	Finished product Specification	In house
	Pack size & Demanded Price	4×15gm can; Decontrolled
	Me-too status	Cefaximin-l Anti Mastitis Spray (Reg # 019906)
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.

	Previous remarks of the Evaluator.	• The firm has provided Aerosol vet section.
	Previous decision(s)	Deferred for clarification of manufacturing of powder formulation in aerosol section (M-288).
	Evaluation by PEC	The firm has submitted that finished product aerosol spray is not in powder form rather it is in liquid form. QC procedures are carried out by taking weight of contents of finished product because after filling liquid and propellant sealing is performed and after that container cannot be opened. Hence final filled volume is quantified by weight.
	Decision: Deferred for further deliberation regarding clarification of manufacturing of powder formulation in aerosol section.	
1824.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Alspray
	Composition	Each gm Contains: Aluminium Powder……40mg
	Diary No. Date of R& I & fee	Dy. No. 2005, 16-01-2018 Rs. 20,000 dated 15-01-2018
	Pharmacological Group	Antiseptic
	Type of Form	Form-5
	Finished product Specification	In house
	Pack size & Demanded Price	210 ml; Decontrolled
	Me-too status	Aluspray Pressurized suspension (Reg # 028560)
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Previous remarks of the Evaluator.	• The firm has provided Aerosol vet section.
	Previous decision(s)	Deferred for clarification of manufacturing of powder formulation in aerosol section (M-288).
	Evaluation by PEC	The firm has submitted that finished product aerosol spray is not in powder form rather it is in liquid form. QC procedures are carried out by taking weight of contents of finished product because after filling liquid and propellant sealing is performed and after that container cannot be opened. Hence final filled volume is quantified by weight.
	Decision: Deferred for further deliberation regarding clarification of manufacturing of powder formulation in aerosol section.	
1825.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Roximax Intrauterine Foam
	Composition	Each 13.4gm Bottle Contains: Rifaximin……..0.10gm
	Diary No. Date of R& I & fee	Dy.No 2009 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	In house
	Pack size & Demanded Price	13.4g; Decontrolled
	Me-too status	Fatroximin Intrauterine Foam. (Reg#048129)
	GMP status	Panel inspection conducted on 13-09-2018 to 14-09-2018 recommends renewal of DML and grant of additional sections.
	Previous remarks of the Evaluator.	• The firm has provided Aerosol vet section.
	Previous decision(s)	Deferred for clarification of manufacturing of powder formulation in aerosol section (M-288).

	Evaluation by PEC	The firm has submitted that finished product aerosol spray is not in powder form rather it is in liquid form. QC procedures are carried out by taking weight of contents of finished product because after filling liquid and propellant sealing is performed and after that container cannot be opened. Hence final filled volume is quantified by weight.
	Decision: Deferred for further deliberation regarding clarification of manufacturing of powder formulation in aerosol section.	

Case no. 03 Registration applications of import cases

a. Deferred Cases (Human)

1826.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Co., Ltd, Address: Office # D-2, 2nd Floor, West Land Trade Centre, Plot # C-5, Block 7/8, KCHSU, Shaheed-e-Millat Road, Karachi
	Detail of Drug Sale License	Address: D-2, 2nd Floor West Land Trade Centre , Plot C-5, Block 7/8, KCHSU, Shaheed e Millat Road, karachi Validity: 09-10-202 Status: License to Sell by way of wholesale
	Name and address of manufacturer	M/s Shijiazhuang No. 4, Pharmaceutical Co., Ltd. Address: No.288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhuang, China
	Name and address of marketing authorization holder	M/s Shijiazhuang No. 4, Pharmaceutical Co., Ltd., Address: No.288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhuang, China
	Name of exporting country	People's Republic of China
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy. No.6662 Dated 21-05-2019
	Fee including differential fee	Rs.100,000/- Dated 21-05-2019
	Brand Name +Dosage Form + Strength	Azofan 250mg dispersible tablet
	Composition	Each dispersible tablet Contains: Azithromycin …….250 mg
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Macrolide antibiotic
	Shelf life	----------
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed
	Detail of certificates attached	Original legalized free sale certificate confirms GMP of them manufacturer. Certifying authority: Hebei Food and Drug Administration, No. 391 Honggi Street, Shijiazhuang, P.R. of China The certificate remains valid till 21-02-2021. <u>Letter of authorization:</u> Letter of authorization showing M/s Zhangjiakou Dongfang Pharmaceutical Co., Ltd as a sales agent in Pakistan for this product has been submitted.
	Remarks of the Evaluator	The firm has submitted 6 months accelerated and 24 months real time Stability study data for following 3 batches as per Zone IV-A conditions.

		350501 350502 350503 Evidence of approval of applied formulation in reference regulatory authority is required. Original letter of authorization / sole agency agreement with product licence holder/ marketing authorization holder is required. Original, legalized CoPP / GMP certificate and free sale certificate are required. The status of product license holder is required to be mentioned. Drug sale license not provided.
	Previous Decision:	Deferred for following observations (M-295) Evidence of approval of applied formulation in reference regulatory authority. Original letter of authorization / sole agency agreement with product licence holder/ marketing authorization holder is required. Original, legalized CoPP / GMP certificate and free sale certificate are required. The status of product license holder. Copy of Drug sale license is required.
	Evaluation by PEC	Letter of authorization has been submitted. Original, legalized free sale certificate stating GMP status of the manufacturer. The product license holder and manufacturer are same.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
1827.	Name and address of Applicant	"M/s RG Pharmaceutica Pvt Ltd. Progressive square No. 703, P.E.C.H.S., Block -6, Shahra-e-Faisal, Karachi"
	Detail of Drug Sale License	Address: Progressive square No. 703, P.E.C.H.S., Block -6, Shahra-e-Faisal, Karachi Validity: 17-01-202 Status: License to Sell by way of wholesale
	Name and address of manufacturer	M/s Livzon (Group) Pharmaceutical Factory Address: No.38, Chuagye Road North, Jinwan District, Zhuhai, Guangdong, P.R. China
	Name and address of marketing authorization holder	M/s Livzon (Group) Pharmaceutical Factory Address: No.38, Chuagye Road North, Jinwan District, Zhuhai, Guangdong, P.R. China
	Name of exporting country	China
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy. No. 402, 12-12-2013,
	Fee including differential fee	Rs.100,000/- Dated 12-12-2013
	Brand Name +Dosage Form + Strength	Maclovir Tablet 125mg
	Composition	Each film coated tablet contains: Famciclovir……125mg
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Antiviral ATC code: J05AB09
	Shelf life	----------
	Demanded Price	899
	Pack size	6's

	International availability	Famciclovir 125mg film coated tablet by M/s Actavis (MHRA approved)
	Me-too status	Could not be confirmed
	Detail of certificates attached	Original Legalized COPP submitted with following details: Certificate No. 20190013 Issued by: Medical products administration of Guangdong Province, West Tower, Tianyu Building No.753, Dongfeng Road Est Guangzhou, Guangdong Province, China Free sale status: COPP confirms free sale status in the exporting country. The certificate remains valid till 28-05-2020. Letter of authorization: The firm has submitted copy of distribution agreement between M/s RG Pharmaceutica (Pvt.) Ltd., Karachi and M/s Livzon Pharmaceutical Group Inc. China. It was valid till 21st January, 2018.
	Remarks of the Evaluator	
	Previous Decision:	Deferred for confirmation of me-too status (M-259).
	Evaluation by PEC	The firm has submitted that me-too for this formulation is not available. The firm has submitted clinical justification for applied formulation.
	Decision: Approved as per policy for inspection of manufacturer abroad. Applicant will submit valid COPP and sole agency agreement as expired during processing of case.	

Case no. 04 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1828.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	DAPLOS 5mg Tablet Each Film coated tablet contains: Dapagliflozin as propanediol monohydrate…….5mg Anti-diabetic In-house specifications	Form 5-D Duplicate, Rs. 50,000/- 12-06-2015 As per P.R.C	Farxiga Tablets by Astrazaneca USFDA GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.
1829.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	DAPLOS 10mg Tablet Each Film coated tablet contains: Dapagliflozin as propanediol monohydrate…….10mg Anti-diabetic	Form 5-D Duplicate, Rs. 50,000/- 12-06-2015 As per P.R.C	Farxiga Tablets by Astrazaneca USFDA GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an

		In-house specifications		acceptable level of compliance with GMP standards.

STABILITY STUDY DATA			
Drug	DAPLOS 5mg Tablet DAPLOS 10mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China		
API Lot No.	DGF-201804001		
Description of Pack (Container closure system)	Alu Alu Foil printed in Unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated : 0 , 3, 6 (months) Real Time: 0 , 3, 6 (Months)		
Products applied	Batch No.	Batch Size	Manufacturing Date
DAPLOS 5mg Tablet	18PD-2389-05-T 18PD-2390-06-T 18PD-2391-07-T	2500 Tablet 2500 Tablet 2500 Tablet	08-2018 08-2018 09-2018
DAPLOS 10mg Tablet	18PD-2409-06-T 18PD-2410-07-T 18PD-2411-08-T	2500 Tablet 2500 Tablet 2500 Tablet	08-2018 08-2018 09-2018
No. of Batches	03		
Date of Submission	4155 (22/04/2019) 4993 (02/05/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DGF-201804001) from M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China issued by China Food and Drug Administration. The certificate is valid till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (700 g) attested by ADC DRAP, Karachi dated 26-06-2018.

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.

Shortcomings communicated	Response of the firm
Justify the dissolution specifications NLT 75% in 30 min since the dissolution specifications of FDA approved product (FARXIGA Tablet) is NLT Q in 15 min. (The value of Q has been defined by FDA as well as USP general chapter is 75% to 80%).	The firm has submitted that after thoroughly reviewing literature we found that Dapagliflozin product is in BCS Class 1 so we have revised our current specifications as NLT 85% in 15 min. We have performed 9 months stability sample kept for long term stability on this revised specification and dissolution results showed more than 85% in 15 minutes. The firm has submitted revised specifications with method of analysis and 9 months dissolution test report.

Previous Decision: Deferred for following: (M-291)
Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 15 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from innovator product [i.e. NLT 75% after 30 minutes].
Evaluation by PEC:
The firm has submitted that we would like to inform that we have now performed dissolution testing on one batch of stability sample after 6 months of accelerated study of Daplos 5mg and 10mg Tablet on accelerated conditions i.e., 40^{o}C and 75% RH and results are found to be within specification limits.
Previous Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches (M-293).
Evaluation by PEC: The firm has submitted stability study data of initial and one month testing with revised dissolution specifications including raw data sheets and chromatograms of following 2 new batches of DAPLOS 5mg Tablet and DAPLOS 10mg Tablet.

Strengths	Batch No	Batch size	Manufacturing date
DAPLOS 5mg Tablet	Batch # 20PD-3138-08-T Batch # 20PD-3139-09-T	2500 Tablets 2500 Tablets	Feb-2020 Feb-2020
DAPLOS 10mg Tablet	20PD-3140-10-T 20PD-3141-11-T	2500 Tablets 2500 Tablets	Feb-2020 Feb-2020

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Daplos (Dapagliflozin) 5mg and 10mg Tablets by M/S PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.1-2/2020-PEC dated 6th July, 2020
Investigation Date and Time: 02nd July, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:
Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi for registration of Daplos (Dapagliflozin) 5mg & Daplos (Dapagliflozin) 10mg Tablets and constituted a three member panel to investigate the authenticity /

genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

4. Prof. Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board).
5. Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi.
6. Ms Sanam Kauser, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Q. No.	Question	Observation by Panel
1.	Do you have documents confirming the import of Dapagliflozin API including approval from DRAP?	The firm has imported Dapagliflozin 700g vide Invoice No. ZY18060601G/W dated June 6, 2018 from M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China for the manufacturing of lab scale batches of Dapagliflozin 5mg and 10mg Tablets. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the import of Dapagliflozin, reference standard and impurity standards?	Firm has documents confirming the import of Dapagliflozin, The API working standard was imported at the time of import of the API.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API and working standard of the API.
5.	Do you have GMP certificate of API manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Huaian Market Supervision Administration, China.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method however, no degradation products are reported by the manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.

10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some quantities of the API and its working standard.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients which includes Daplos 5mg Tablet, Super Tab 21AN (Lactose Anhydrous), Microcrystalline cellulose PH.102, Crospovidone, Colloidal Silicon Dioxide (Aerosil 200), Magnesium Stearate and Opadry Yellow II 85G62338 has been used for coating and Daplos 10mg Tablet, Super Tab 21AN (Lactose Anhydrous), Microcrystalline cellulose PH.102, Crospovidone, Colloidal Silicon Dioxide (Aerosil 200), Magnesium Stearate and Opadry White II 85G68918, Lake of Quinoline Green has been used for coating.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Dapagliflozin 5mg and 10mg Tablets?	The firm has written and authorized protocols for the development of Dapagliflozin 5mg and 10mg Tablets.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipient compatibility studies as the composition of their tablets is similar to that of the innovator product (Forxiga Tablets 5mg and 10mg manufactured by M/s Astrazeneca AB).
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of Daplos 5mg and 10mg Tablet with Forxiga Tablets 5mg and 10mg manufactured by M/s Astrazeneca AB respectively. Similarity factor for Dapagliflozin 5mg Tablet are as follows: a. Buffer pH 1.2 (Drug releases more than 85% in 15minutes so no need to calculate F2). b. Acetate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2). c. Phosphate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2). Similarity factor for Dapagliflozin 10mg Tablet are as follows: a. Buffer pH 1.2 (Drug releases more than 85% in 15minutes so no need to calculate F2). b. Acetate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2). c. Phosphate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2).

17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment available in product development section for development of Dapagliflozin 5mg & 10mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Dapagliflozin 5mg and 10 mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration/ re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development with suitable knowledge and training in product development. 02 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Dapagliflozin 5mg and 10mg Tablets as required?	The firm has manufactured three stability batches for the stability studies of: Dapagliflozin 10mg Tablets with Batch Numbers: 18PD-2409-06-T 18PD-2410-07-T 18PD-2411-08-T Dapagliflozin 5mg Tablets with Batch Numbers: 18PD-2389-05-T 18PD-2390-06-T 18PD-2391-07-T Further, as per decision of Board in 293 DRB held on 6 – 8 January, 2020, firm has manufactured two fresh batches each for both strength of Dapagliflozin 5mg and 10mg Tablets. Dapagliflozin 10mg Tablets with Batch Numbers: 20PD-3140-10-T 20PD-3141-11-T Dapagliflozin 5mg Tablets with Batch Numbers: 20PD-3138-08-T 20PD-3139-09-T All batches have been produced with batch size of 2500 tablets.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing batch size is according to DRAP guidelines
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation studies.

27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies have not been done, however, validation of the method has been performed.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Dapagliflozin and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Dapagliflozin and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation studies.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Dapagliflozin testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Accelerated stability testing is over whereas in real time studies 12 months testing have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Dapagliflozin 5mg & 10mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Dapagliflozin tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.
37.	**Specific Queries by PEC/Board** To verify and report the submitted stability study data of 2 batches of Daplos 5mg and 10mg Tablets each.	As per direction of the PEC, stability data of Daplos 5mg tablets and Daplos 10mg tablets with following details were checked. 1. Daplos 5mg tablets: B.No. 20PD3138-08-T (2500 tablets) and B.No. 20PD3139-09-T (2500 tablets). 2. Daplos 10mg tablets: B. No. 20PD-3140-10-T (2500 tablets) and B. No. 20PD-3141-11-T (2500 tablets). The stability data for all these batches at 0 month and 1 month is satisfactory.

Conclusions:

3. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Daplos (Dapagliflozin) 5mg and 10mg Tablets is verifiable to satisfactory level.

4. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Dapagliflozin 5mg and 10mg Tablets.

Recommendations:

The firm may kindly be granted necessary registration of Dapagliflozin 5mg and 10mg Tablets.

Decision: Registration Board decided to approve registration of Daplos 5mg and 10mg Tablets with Innovator's specifications by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
1830.	M/s Neutro Pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.	Sinacalcet 30mg Tablet Each film coated tablet contains: Cinacalcet as hydrochloride……30mg Anti-parathyroid Manufacturer's	Form 5 Dy. No.6882 dated 22-02-2018 Rs. 20,000/- dated 21-02-2018, 14's, 28's, 30's, 84's; As per SRO	USFDA approved GMP inspection dated 18-07-2017 showed that the firm has maintained fair level of compliance with GMP.
1831.	M/s Neutro Pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.	Sinacalcet 60mg Tablet Each film coated tablet contains: Cinacalcet as hydrochloride……60mg Anti-parathyroid Manufacturer's	Form 5 Dy. No.6881 dated 22-02-2018 Rs. 20,000/- dated 21-02-2018, 14's, 28's, 30's, 84's; As per SRO	USFDA approved GMP inspection dated 18-07-2017 showed that the firm has maintained fair level of compliance with GMP.
1832.	M/s Neutro Pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.	Sinacalcet 90mg Tablet Each film coated tablet contains: Cinacalcet as hydrochloride……90mg Anti-parathyroid Manufacturer's	Form 5 Dy. No.8625 dated 08-03-2018 Rs. 50,000/- dated 07-03-2018, 14's, 28's, 30's, 84's; As per SRO	USFDA approved GMP inspection dated 18-07-2017 showed that the firm has maintained fair level of compliance with GMP.

STABILITY STUDY DATA

Drug	Sinacalcet 30mg Tablet Sinacalcet 60mg Tablet Sinacalcet 90mg Tablet
Name of Manufacturer	M/s Neutro Pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore.
Manufacturer of API	M/s Fuan Pharmaceutical (Group) Co., Ltd, China

API Lot No.	L-1703180301		
Description of Pack (Container closure system)	Blistered as 10's × 3 packed in unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4& 6 (months)		
Products applied	Batch No.	Batch size	Manufacturing date
Sinacalcet 30mg Tablet	SIN-FC-30-001-18 SIN-FC-30-002-18 SIN-FC-30-003-18	240 + 280 Tablets 240 + 280 Tablets 240 + 280 Tablets	09/2018 11/2018 11/2018
Sinacalcet 60mg Tablet	SIN-FC-60-001-18 SIN-FC-60-002-18 SIN-FC-60-003-18	240 + 280 Tablets 240 + 280 Tablets 240 + 280 Tablets	09/2018 11/2018 11/2018
Sinacalcet 90mg Tablet	SIN-FC-90-001-18 SIN-FC-90-002-18 SIN-FC-90-003-18	240 + 280 Tablets 240 + 280 Tablets 240 + 280 Tablets	09/2018 11/2018 11/2018
No. of Batches	03		
Date of Submission	17698 (17-09-2019) 17698 (17-09-2019) 22419 (30-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch #L-1703180301) from M/s Fuan Pharmaceutical (Group) Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Chongqing Daguan Economic Development Area Management Committee. It is valid until 03/03/2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Cinacalcet HCl (2Kg), attested by ADC DRAP, Lahore dated 18-07-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

Sr. No.	Observations	Response of the firm
1.	GMP certificate from concerned regulatory authority is required to be submitted.	The firm submitted GMP certificate of API manufacturer with new name i.e., M/s Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd, China. However, certificate of analysis submitted was of previous API manufacturer. Similarly, name and address of API manufacturer mentioned on invoice cleared by AD (I&E), Lahore was of different name. **Certificate of Analysis**: M/s. Fuan Pharmaceutical (Group), Co. Ltd., No.1, Huanan Yi Road, Changhsou District, Chongqing 401254, P.R. China. **GMP certificate:** M/s Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd., No. 1, Huanan Yi Road, Changshou District, Chongqing 401254, China. **Invoice:** M/s Fuan Group Chongqing Kingsday Pharmaceutical Co Ltd., No. 2, Huangyang Road, Yubei District, 401120, China.
2.	Finished product specifications alongwith details of analytical methods are required to be submitted.	Submitted
3.	Justification of dissolution limits of NLT 75% is required. Moreover, details of analytical procedures of dissolution and assay are required.	The firm revised dissolution limit to 80% (Q) with following dissolution test conditions: **Dissolution medium**: 0.01N HCl **Time**: 45min **Apparatus**: Type II (Paddle apparatus) **Temperature**: 36.5°C to 37.5°C **RPM**: 75
4.	Justification of using UV method for both assay and dissolution testing.	The firm developed HPLC method for assay determination during stability study. The firm submitted following: • Analytical method validation report • Performance of assay test on HPLC at 9th month and 12th month time points of stability studies. • Summary sheets, relevant chromatograms and raw data sheets were submitted.

Decision: Registration Board decided to reject the applications of Sinacalcet 30mg Tablet, Sinacalcet 60mg Tablet and Sinacalcet 90mg Tablet of M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road Lahore due to following reasons:

- **Firm has performed assay test of drug product on UV-Visible spectrophotometer although it was required to be performed on HPLC method either as per innovator product or as per method of drug substance manufacturer as evident from the details of COA of drug substance.**
- **Firm adopted non-validated HPLC method at 9-month testing point which cannot cover the accelerated stability studies for the whole 6 months period and real time stability studies till 9th month time point.**
- **Firm used testing method derived from literature for testing their product without performing validation studies. At 9-month time point, the firm submitted that they have used validated HPLC method for testing of stability batches. In actual, the firm submitted analytical method validation report of "Assay by UV-visible spectrophotometer".**

b. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
1833.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Prucal Tablet 1mg Each Film Coated Tablet Contains: Prucalopride (as succinate).....1mg Other drugs for constipation ATC code: A06AX05	Form-5D Dy.No 4630 08-02-2018 Rs.50,000 26-01-2018 As per SRO	Motegrity Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.
1834.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Prucal Tablet 2mg Each Film Coated Tablet Contains: Prucalopride (as succinate)……2mg Other drugs for constipation ATC code: A06AX05	Form 5-D Dy No. 20086 06-11-2017 PKR 50,000/- (31-10-2017) (**Duplicate** dossier verified from R&I) As per SRO	

STABILITY STUDY DATA			
Manufacturer of API	Symed Labs Limited Sy No. 744, 745 & 751, Mandollagudem village, Choutuppal Mandal, Yadadri District, Telangana India.		
API Lot No.	PCS 0010617		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
PRUCAL TABLET 1MG			
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	12-2017	02-2018	02-2018
Date of Initiation	10-01-2018	09-02-2018	09-02-2018
PRUCAL TABLET 2MG			
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	09-2017	01-2018	01-2018
Date of Initiation	30-11-2017	09-02-2018	09-02-2018
No. of Batches	03		
Date of submission	30389 (15-01-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate issued by Drugs Control Administration Government of Telangana. Copy of GMP certificate issued by DCA Telangana for the M/s Symed Labs Limited, Unit-VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollaguden (Village), Choutuppal (Mandal), Yadadri District, Telangana, India and valid upto 10-2021 has been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 14-09-2017 specifying import of 15g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 14-09-2017 specifying import of 15g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice.

3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate issued by Drugs Control Administration Government of Telangana. Copy of GMP certificate issued by DCA Telangana for the M/s Symed Labs Limited, Unit-VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollaguden (Village), Choutuppal (Mandal), Yadadri District, Telangana, India and valid upto 10-2021 has been submitted.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: **PRUCAL TABLET 1MG** TF-01: 730 Tablets TF-02: 213 Tablets TF-03: 213 Tablets **PRUCAL TABLET 2MG** Trial # 01: 725 Tablets Trial # 02: 460 Tablets Trial # 03: 460 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 75±5%RH) stability studies reports of three batches of API's. The real time stability study data is till 60 months.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the

		innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of their product against the Resolor Tablet of Janssen. The drugs show more than 85% release in 15 minutes at all media.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
The commercial invoice for import of API is of 28-03-2017, while the manufacturing date of the API lot used in stability studies is June 2017. Justify how a material which is manufactured in June 2017 can be imported in March 2017. Further justify why the commercial invoice is not attested by AD (I&E) DRAP field office.	We have procured API through invoice dated 14-09-2017 and the manufacturing date of those API batch was June 2017. We have also procured small quantity of API for trial batches and mistakenly attached its commercial invoice. Firm has submitted commercial invoice dated 14-9-2017. Firm has submitted that the material was procured 2 years back and at that time we imported it through DHL and have also submitted copy of DHL invoice.
Provide valid GMP certificate of API manufacturer since the submitted certificate is expired.	Firm has submitted GMP certificate (No. 2824/A3/2018) issued by Drugs Control Administration Government of Telangana. Copy of GMP certificate issued by DCA Telangana for the M/s Symed Labs Limited, Unit-VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollaguden (Village), Choutuppal (Mandal), Yadadri District, Telangana, India and valid upto 10-2021 has been submitted.
As per the quality review report of innovator product, the particle size of API should be carefully controlled to develop a product having acceptable performance, justify your formulation development without controlling particle size.	Prucalopride succinate lies in BCS class I so its solubility and permeability is high, further we have used micronized API where the particle size was controlled by API manufacturer. Due to intrinsic properties of API as well as controlled particle size the drug dissolved more than 80% in 20 minutes.
Justify the dissolution specification NLT 75%(Q) after 45 minutes, since the USFDA chemistry review document of the innovator product specify dissolution specifications NLT (Q) at 20 minutes.	We have selected dissolution specifications NLT 75%(Q) after 45 minutes based on recommendations of general chapter of USP and keeping in view the immediate release nature of the drug product. Comparative dissolution profile was also determined which also show comparable results. CDP show more than 80% relese in 20 minutes. Now after reviewing the innovator product we have revised our specifications to NLT 75%(Q) after 20 minutes as per the decision of 293rd meeting of Registration Board.

Decision: Registration Board decided to defer the case for submission of COA, Form-3 and Form-7 for import of API i.e., Prucalopride as succinate.

1835.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Indazin 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin…5mg"
	Diary No. Date of R& I & fee	Dy. No 11495 dated 05-03-2019, Rs.20,000/- Dated 05-03-2019, 30,000/- dated 17-08-2020
	Pharmacological Group	SGLT2 Inhibitor
	Type of Form	Form-5

	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	N/A
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator	Stability studies data as per directions of 278th meeting is required. Differential Fee of Rs. 30,000/- is required.
	Previous Decision(s)	Deferred for submission of stability data as per directions of 278th meeting of Registration Board (M-291).
	Evaluation by PEC	The firm has submitted stability study data alongwith exemption data from onsite inspection.

STABILITY STUDY DATA

Drug	INDAZIN 5MG TABLET		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi		
Manufacturer of API	M/s Lianyungang Jari pharmaceutical Co., Ltd. No.18, Zhenhua Road, Lianyungang, China		
API Lot No.	20170421		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	TR-1/Dap 5mg Tab	TR-2/Dap 5mg Tab	TR-3/Dap 5mg Tab
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	13-07-2019	13-07-2019	13-07-2019
No. of Batches	03		
Date of Submission	11-05-2020 (Dy. No. 10545)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents to Be Provided	Status
Certificate of analysis of API.	Copy of COA of Dapagliflozin Propanediol monohydrate (batch # 20170421) from M/s Lianyungang Jari Pharmaceutical Co., Ltd. China is submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of Manufacturing license of M/s Lianyungang Jari Pharmaceutical Co., Ltd. China issued by Jiangsu Food and Drug Administration, China valid upto 31-12-2020.
Protocols followed for conduction of stability study	Yes

and details of tests.	
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (0.175Kg), attested by Assistant Director (I & E) DRAP, Karachi dated 20-06-2017 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 11-05-2020 (Dy. No. 10545)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their products "Canzin 100mg Tablet and Canzin 200mg Tablet", which were presented in 289th meeting of Registration board. Registration Board decided to approve registration of above products of M/s Indus Pharma (Pvt) Ltd., Karachi. Date of inspection : 14-03-2019 According to the report generated following points were confirmed a) HPLC Software is 21 CFR part 11 compliant where all user levels were properly defined b) The firm has stability chambers are equipped with data loggers and centralized controlling software.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (0.175Kg), attested by Assistant Director (I & E) DRAP, Karachi dated 20-06-2017 has been submitted.
3.	Documents for the procurement of reference standard and impurity standards.	Not submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of Manufacturing license of M/s Lianyungang Jari Pharmaceutical Co., Ltd. China issued by Jiangsu Food and Drug Administration, China valid upto 31-12-2020.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	• The firm has submitted copy of COA of Dapagliflozin Propanediol monohydrate (batch # 20170421) from M/s Lianyungang Jari Pharmaceutical Co., Ltd. China is submitted.

<table>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for Pharmaceutical Product Development”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TR-1/Dap 5mg Tab</td><td>2500 Tabs</td><td>04-2018</td></tr>
<tr><td>TR-2/Dap 5mg Tab</td><td>2500 Tabs</td><td>04-2018</td></tr>
<tr><td>TR-3/Dap 5mg Tab</td><td>2500 Tabs</td><td>04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Batch Size</th><th>Tablets used for stability testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>TR-1/Dap 5mg Tab</td><td>2500 Tabs</td><td>32 packs</td><td>116 packs</td></tr>
<tr><td>TR-2/Dap 5mg Tab</td><td>2500 Tabs</td><td>32 Packs</td><td>122 packs</td></tr>
<tr><td>TR-3/Dap 5mg Tab</td><td>2500 Tabs</td><td>32 packs</td><td>123 packs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Dapagliflozin propanediol monohydrate.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Dapagliflozin 5mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted 06 months accelerated and 24 months real time stability study data of three batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that we used all the ingredients same as used in innovator product Farxiga Tablet 5mg.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution study of Dapagliflozin 5mg Tablet with Farxiga 5mg Tablet (Batch # MV947) in three recommended mediums at pH 1.2, pH 4.5, pH 6.8. Dissolution profiles of both products were considered similar.</td></tr>
</table>

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Observations	Response of the applicant
Documents for the procurement of reference standard and impurity standards.	The firm has submitted that we have imported reference standard alongwith API without invoice. The API manufacturer of Dapagliflozin propanediol monohydrate does not define any specific impurity but define only unknown impurities in the analysis. Analysis of indazin 5mg Tablet was done and found no unknown impurity at accelerated and long term storage conditions.
Justify dissolution specifications NLT 75% (Q) in 20 min since dissolution specifications of innovator product Farxiga 5mg Tablet is NLT Q in 15min.	The firm has submitted revised testing data with dissolution specifications NLT 85% in 15 min at initial and 3rd month time point at both accelerated and real time stability conditions for 2 batches alongwith raw data and chromatograms.
Certificate of analysis of reference standards and impurity standards are required.	The firm has submitted copy of COA of working standard of Dapagliflozin propanediol monohydrate.
Record of remaining quantities of stability batches i.e., Tablets used for stability testing and remaining quantities of tablets are not mentioned in submitted BPRs.	The firm has submitted record of remaining quantities of stability batches.

Decision: Registration Board decided to approve registration of INDAZIN 5mg Tablet with Innovator's specifications by M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1836.	Name and address of manufacturer / Applicant	M/s Scotmann pharmaceuticals, 5-D, I-10/3, Industrial area, Islamabad
	Brand Name +Dosage Form + Strength	Vorscot Tablets 15mg
	Composition	Each film coated tablet contains: Vortioxetine hydrobromide eq. to vortioxetine……..15mg
	Diary No. Date of R& I & fee	42031, -07-12-2018, Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Other Antidepressants
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO; 1× 10's, 3× 10's, 6× 10's & 9× 10's
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX 15mg Tablet (USFDA approved)
	Me-too status	N/A
	GMP status	Panel inspection dated 10-10-2018 & 17-10-2018 recommends grant of GMP certificate.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Vorscot Tablets 15mg
Name of Manufacturer	M/s Scotmann pharmaceuticals, 5-D, I-10/3, Industrial area, Islamabad
Manufacturer of API	M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China
API Lot No.	20180203
Description of Pack (Container closure system)	Alu-Alu Blister

Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 months Real Time: 0,3,6 months		
Batch No.	T#01	T#02	T#03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	18-06-2018	20-06-2018	21-06-2018
Date of Initiation	26-06-2018	26-06-2018	26-06-2018
No. of Batches	03		
Date of Submission	24-02-2020 (Dy. No.2566)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
Certificate of analysis of API.	Copy of COA of Vortioxetine hydrobromide (batch # 20180203) from M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China is submitted. In addition, COAs of following from API supplier has been submitted. Working standard Oxide impurity 2,6 impurity
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China issued by Liangyungang Drug Administration valid upto 11-04-2024.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine hydrobromide (500g) attested by Assistant Director (I & E) DRAP, Islamabad dated 16-05-2018. The firm has submitted copy of invoice for the purchase of following: Vortioxetine HBr Working standard (1gm) Oxide Impurity (Batch # VTF 20180101, 10mg) 2,6- Impurity (Batch # VT2620170101, 10mg)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 24-02-2020 (Dy. No.2566)

Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "DASCOT 60mg Tablet", which was presented in 278th meeting of Registration board. Date of inspection : 26-01-2018 According to the report, following points were confirmed a) The HPLC software is 21CFR Compliant. b) Continuous monitoring and power supply are available for stability chambers alongwith data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine hydrobromide (500g) attested by Assistant Director (I & E) DRAP, Islamabad dated 16-05-2018.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of invoice for the purchase of following: Vortioxetine HBr Working standard (1gm) Oxide Impurity (Batch # VTF 20180101, 10mg) 2,6- Impurity (Batch # VT2620170101, 10mg)
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China issued by Liangyungang Drug Administration valid upto 11-04-2024.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA of Vortioxetine hydrobromide (batch # 20180203) from M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China is submitted. In addition, COAs of following from API supplier has been submitted. Working standard Oxide impurity 2,6 impurity
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for the procurement of excipients used in product development
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for Pharmaceutical Product Development".
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Manufacturing protocols of following 03 Batches: Batch No. / Batch Size / Mfg. Date T#01 / 1500 Tabs / 06-2018 T#02 / 1500 Tabs / 06-2018 T#03 / 1500 Tabs / 06-2018
11.	Record of remaining quantities of stability batches.	Trial No / Batch Size / Tablets used for / Remaining Quantities of tablets

				stability testing	
			T#01	1500 Tabs	448	224
			T#02	1500 Tabs	448	224
			T#03	1500 Tabs	448	224
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Vortioxetine hydrobromide.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Vorscot Tablet 15mg" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted 6 months accelerated and 24 months real time stability study data of three batches of vortioxetine hydrobromide.
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has justified Drug-Excipient compatibility studies by giving references from Hand book of excipients.
18.	Record of comparative dissolution data.	The firm has submitted that we claimed exemption from CDP since reference product is not available in Pakistan.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Sr. No.	Observations	Response of the applicant
1.	GMP certificate issued to API manufacture is of city administration. It is required to submit GMP certificate from provincial or federal administration.	The firm has submitted copy of GMP certificate issued by China Food and Drug Administration, China. It was valid till 19-11-2019.
2.	Confirmation of Polymorphic form of Vortioxetine HBr used in stability studies is required.	The firm has submitted revised COA from API manufacturer stating polymorphic **Form B** of vortioxetine HBr. The confirmation of polymorphic form was done by XRD technique.
3.	Justify dissolution specifications NLT 85% dissolved in 45 min since dissolution acceptance criteria for innovator product (TRINTELLIX) is NLT Q in 30 min	The firm has revised dissolution specifications in accordance with innovator i.e., NLT 85% of the labeled amount of vortioxetine in 30min and will perform testing for remaining time points with revised limits. Moreover, commercial batch will also be tested as per innovator specifications.
4.	You have not performed uniformity of dosage unit by content uniformity (HPLC), as recommended by the USP general chapter <905> since contents of Votioxetine	The firm has performed uniformity of dosage unit by content uniformity (HPLC).

	hydrombromide in formulation are less than 25%.	

Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications fall within the definition of immediate release drug product and approved registration of following drug with innovator's specification, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 30 minutes for commercial batches.**
- **Vorscot Tablets 15mg**

Furthermore, manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1837.	Name and address of manufacturer / Applicant	M/s Scotmann pharmaceuticals, 5-D, I-10/3, Industrial area, Islamabad
	Brand Name +Dosage Form + Strength	Vorscot Tablets 5mg
	Composition	Each film coated tablet contains: Vortioxetine hydrobromide eq. to vortioxetine……..5mg
	Diary No. Date of R& I & fee	42028, 07-12-2018, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Other Antidepressants
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO; 1× 10's, 3× 10's, 6× 10's & 9× 10's
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX 5mg Tablet (USFDA approved)
	Me-too status	N/A
	GMP status	Panel inspection dated 10-10-2018 & 17-10-2018 recommends grant of GMP certificate.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Vorscot Tablets 5mg		
Name of Manufacturer	M/s Scotmann pharmaceuticals, 5-D, I-10/3, Industrial area, Islamabad		
Manufacturer of API	M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China		
API Lot No.	20180203		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,3,6 months		
Batch No.	T#01	T#02	T#03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	21-06-2018	22-06-2018	24-06-2018
No. of Batches	03		
Date of Submission	24-02-2020 (Dy. No.2566)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	**Status**

Certificate of analysis of API.	Copy of COA of Vortioxetine hydrobromide (batch # 20180203) from M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China is submitted. In addition, COAs of following from API supplier has been submitted. Working standard Oxide impurity 2,6 impurity
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China issued by Liangyungang Drug Administration valid upto 11-04-2024.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine hydrobromide (500g) attested by Assistant Director (I & E) DRAP, Islamabad dated 16-05-2018. The firm has submitted copy of invoice for the purchase of following: Vortioxetine HBr Working standard (1gm) Oxide Impurity (Batch # VTF 20180101, 10mg) 2,6- Impurity (Batch # VT2620170101, 10mg)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 24-02-2020 (Dy. No.2566)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "DASCOT 60mg Tablet", which was presented in 278th meeting of Registration board. Date of inspection : 26-01-2018 According to the report, following points were confirmed a) The HPLC software is 21CFR Compliant. b) Continuous monitoring and power supply are available for stability chambers alongwith data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine hydrobromide (500g) attested by Assistant Director (I & E) DRAP, Islamabad dated 16-05-2018.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of invoice for the purchase of following:
Vortioxetine HBr Working standard (1gm)
Oxide Impurity (Batch # VTF 20180101, 10mg)
2,6- Impurity (Batch # VT2620170101, 10mg)</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP Certificate for M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China issued by Liangyungang Drug Administration valid upto 11-04-2024.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Copy of COA of Vortioxetine hydrobromide (batch # 20180203) from M/s Liangyungang Jari Pharmaceutical Co., Ltd, Jiangsu, China is submitted.
In addition, COAs of following from API supplier has been submitted.
Working standard
Oxide impurity
2,6 impurity</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for Pharmaceutical Product Development”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>T#01</td><td>1500 Tabs</td><td>06-2018</td></tr>
<tr><td>T#02</td><td>1500 Tabs</td><td>06-2018</td></tr>
<tr><td>T#03</td><td>1500 Tabs</td><td>06-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Trial No</td><td>Batch Size</td><td>Tablets used for stability testing</td><td>Remaining Quantities of tablets</td></tr>
<tr><td>T#01</td><td>1500 Tabs</td><td>448</td><td>224</td></tr>
<tr><td>T#02</td><td>1500 Tabs</td><td>448</td><td>224</td></tr>
<tr><td>T#03</td><td>1500 Tabs</td><td>448</td><td>224</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Vortioxetine hydrobromide.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Vorscot Tablet 15mg” along with Stability Study Reports.</td></tr>
</table>

15.	Reports of stability studies of API from manufacturer.	The firm has submitted 6 months accelerated and 24 months real time stability study data of three batches of vortioxetine hydrobromide.
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has justified Drug-Excipient compatibility studies by giving references from Hand book of excipients.
18.	Record of comparative dissolution data.	The firm has submitted that we claimed exemption from CDP since reference product is not available in Pakistan.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Sr. No.	Observations	Response of the applicant
1.	GMP certificate issued to API manufacture is of city administration. It is required to submit GMP certificate from provincial or federal administration.	The firm has submitted copy of GMP certificate issued by China Food and Drug Administration, China. It was valid till 19-11-2019.
2.	Confirmation of Polymorphic form of Vortioxetine HBr used in stability studies is required.	The firm has submitted revised COA from API manufacturer stating polymorphic Form B of vortioxetine HBr. The confirmation of polymorphic form was done by XRD technique.
3.	Justify dissolution specifications NLT 85% dissolved in 45 min since dissolution acceptance criteria for innovator product (TRINTELLIX) is NLT Q in 30 min	The firm has revised dissolution specifications in accordance with innovator i.e., NLT 85% of the labeled amount of vortioxetine in 30min and will perform testing for remaining time points with revised limits. Moreover, commercial batch will also be tested as per innovator specifications.
4.	You have not performed uniformity of dosage unit by content uniformity (HPLC), as recommended by the USP general chapter <905> since contents of Votioxetine hydrombromide in formulation are less than 25%.	The firm has performed uniformity of dosage unit by content uniformity (HPLC).

Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications fall within the definition of immediate release drug product and approved registration of following drug with innovator's specification, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 30 minutes for commercial batches.**
- **Vorscot Tablets 5mg**

Furthermore, manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data (Deferred cases)

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition,	Type of Form, Initial Diary & Date, Fee (including differential fee),	International Availability / Local Availability GMP Inspection Report Date & Remarks

		Pharmacological Group, Finished Product Specification	Demanded Price / Pack size	
1838.	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.	Tigrelor 90mg tablet Each film-coated tablet contains: Ticagrelor...90mg (Platelet Aggregation Inhibitor) Innovator's specifications	Form- 5 Dy.No.931 Dated: 22-12-2014 Rs.50,000/- (17-12-2014) 2 x 10's; as per SRO	Brilinta 90 mg film-coated tablets of M/s AstraZeneca UK Limited (MHRA Approved) / Not applicable Last GMP inspection was conducted on 12-12-2017 and GMP certificate was issued on 15-12-2017.

STABILITY STUDY DATA			
Drug	Tigrelor 90mg tablet		
Name of Manufacturer	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-TG-201709061		
Description of Pack (Container closure system)	Alu- Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (month) Real Time: 0, 3, 6, 9, 12 (months)		
Batch No.	17PD064TICT05	17PD081TICT06	17PD089TICT07
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Nov-2017	Dec-2017	Dec-2017
Date of Initiation	29-01-2018	29-01-2018	30-01-2018
No. of Batches	04		
Date of Submission	16-08-2018 (27937)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
1.	CoA of API	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Firm has submitted 6 months accelerated and 12 months real time stability study data of four batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 02-07-2019 vide diary no. 10339

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Apixa 2.5mg and 5mg (Apixaban) Tablets", which was presented in 289th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Pharmatec Pakistan (Private) Ltd, Karachi. Date of inspection: 30-04-2019 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted COAs of following working standards & impurity Standards : Ticagrelor working standard (B # WS201603001) Ticagrelor working standard (B # WTG01-170401) Impurity standards TG16 WRS (B# WTG05-170401) De-Ethoxyl of TG WRS (B# WTG06-170401)
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for evaluation of vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.

<table>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Ticagrelor 90mg Tablet”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>30-01-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Trial No</td><td>Total no. of Tablets For stability testing</td><td>Tablets used for testing</td><td>Remaining Quantities of tablets</td></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>1800 Tablets</td><td>700 tablets</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 29-11-2017 to</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Ticagrelor.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ticagrelor 90mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Nantong Chanyoo Pharmatech Co., Ltd. China. The storage conditions for real time stability data are 25±2ºC/60±5%RH.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The compatibility of Ticagrelor 900mg (API) and 40mg Sodium lauryl sulphate (Excipient) was studied by HPLC analytic techniques after storage of mixture under accelerated conditions. HPLC analysis of these mixtures has not shown any significant physical and chemical instability. Hence the study concludes that Ticagrelor and sodium lauryl sulphate are compatible.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Ticagrelor 90mg tablet and Brilinta 90mg tablet. The results suggest similarity factor (f2) > 50 and difference factor (f1) < 15 in all three media.</td></tr>
</table>

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Ticagrelor 90mg Tablet" from.

Sr. No.	Observations communicated	Response by the applicant
1.	Digital data logger record does not cover the duration of stability study data. Clarification is required.	Digital logger sheets which cover the duration stability study data.
2.	Justification is required for preparation of four batches for the purpose of carrying out stability studies.	The first batch exhibiting the batch number 17PD048TICT04, is the pre-formulation batch, the very initial batch developed at every step of formulation development, this supports in making decision. These steps include process feasibility studies, formulation optimization and manufacturing process.
3.	Audit trail reports of only one date are submitted. It is important to submit the audit trail reports at all time points of stability studies as well as comparative dissolution study.	Audit trail on the testing time point is submitted.
4.	Polymorphic formof Ticagrelor API is required to be submitted.	The firm has submitted that polymorphic form-II was used and further stated that same form of molecule is discussed in the patent of Astra Zeneca. The form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction.

Storage conditions under which stability studies were conducted are at 25ºC±2ºC/60%±5% RH.
Previous Decision: Deferred for submission of scientific justification for conducting API stability studies at storage conditions of 25ºC±2ºC/60%±5% RH.
Evaluation by PEC: The firm has submitted that internationally API stability studies are conducted at 25ºC±2 ºC/60%±5%RH because majority of API manufacturer supplies their product to international market. When we receive APIs, we keep them in controlled temperature i.e., 25ºC. When we manufacture our finished product with these APIs, we use to conduct stability studies of our products according to our stability Zone i.e., Zone IVA.

Previous Decision: Registration Board deferred the case for submission of valid GMP certificate of M/s Nantong Chanyoo, Jiangsu province, China, issued by relevant Provincial or state Regulatory authority since the Nantong Food and Drug Administration is not the relevant provincial regulatory authority (M-293).
Response of the firm: Firm has submitted copy of "License for Drug production" issued by the Jiangsu Food and Drug Administration in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., China with License number "S. 20160512" and valid upto 31-12-2020.
The above cited certificate has been verified from the following web link of National Medical Product Administration of China:
http://app1.sfda.gov.cn/datasearchcnda/face3/base.jsp?tableId=34&tableName=TABLE34&title=%D2%A9%C6%B7%C9%FA%B2%FA%C6%F3%D2%B5&bcId=152911762991938722993241728138 .

Deferred for following submissions (M-294):

- Submission of real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product as per the decision of 290th meeting of Registration Board since the firm has used API whose stability testing has not been done as per the conditions of Zone IV-A.
- Scientific justification for performance of drug excipient compatibility studies with only 1 excipient (i.e. Sodium lauryl sulphate).

- Status whether form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction by M/s Pharmatec or API manufacturer

Evaluation by PEC: The firm has submitted following:

- Stability study data of API as per Zone IV-A.
- Drug Excipient compatibility was conducted and assessed through HPLC. Binary mixtures of excipient and drug substance at a ratio 1:1 ratio in the solid state were prepared. Results showed no interference/degradant was detected with any of the excipient used.
- Crystalline Form-II of Ticagrelor is confirmed by melting points & X-Ray diffraction as per DMF of API manufacturer.

Decision: Registration Board decided to approve registration of Tigrelor 90mg Tablet with Innovator's specifications by M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
1839.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Tofacit 5mg Tablet Each Film Coated tablet Contains: Tofacitinib (as citrate) ……5mg Selective immunosuppressants ATC code: L04AA29	Form-5 Dy. No. 34109: 15.10.2018 PKR 20,000/-: 04.08.2018 As per SRO	XELJANZ 5 mg film-coated tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

Case history:

Decision of 290th meeting of Registration Board:

Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies and generic / me-too status which were adopted by the Registration Board in its 275th meeting.

Now the firm has submitted the reference and generic evidence which is as under:

Reference status "XELJANZ 5 mg film-coated tablets (Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium"

Generic/me-too status " Xeljanz Film Coated Tablet 5mg of M/s Pfizer"

Decision of 293rd meeting of Registration Board:

Deferred for further deliberation regarding stability data.

The stability data of 3 batches have been submitted by the firm

STABILITY STUDY DATA

Manufacturer of API	Kaifeng Pharmaceutical (Grp)Co. Ltd. No. 1 Yunan Street Kaifeng		
API Lot No.	KFX171203		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
Batch No.	TF-01	TF-02	TF-03

Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	11-2018	12-2018	12-2018
Date of Initiation	14-11-2018	20-12-2018	20-12-2018
Date of submission	4648 (16-03-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number 783242202418.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number

		783242202418.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 70 Tablets TF-02: 98 Tablets TF-03: 108 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated stability studies & long term stability studies reports of three batches of API.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of their product against the Xeljanz Tablet. The drugs show more than 85% release in 15 minutes at all media.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Submit protocols for stability studies	Firm has submitted protocols for stability studies.

You have provided dissolution specifications as NLT 75% in 15 minutes without specifying the value of "Q".	Firm has submitted revised dissolution specifications with acceptance criteria NLT 75%(Q) after 15 minutes
Submit stability study data of API	Firm has submitted the stability study data of API for three batches.

Decision: Registration Board decided to approve registration of Tofacit 5mg Tablet (Tofacitinib, Selective immunosuppressants, ATC code: L04AA29) with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case no. 05: Registration applications of locally manufacturing drugs (human) submitted on CTD format

1840.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18270 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..12.5mg Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 12.5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: M/s. Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma

		Tu), Fuxin City, Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1841.	Name, address of Applicant / Marketing	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub

	Authorization Holder	River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18269 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications,

		analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ^{o}C ±2^{o}C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30^{o}C±2^{o}C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1842.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18268 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 500mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study

		data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1843.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20014 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------

	The status in reference regulatory authorities	Synjardy 5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes

		in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1844.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20013 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ^{o}C ±2^{o}C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30^{o}C±2^{o}C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1845.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18267 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	----------
	The status in reference regulatory authorities	Synjardy 5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India		
API Lot No.	Empagliflozin: Metformin hydrochloride:		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Strengths applied	Batch No	Batch size	Manufacturing date
EMPOLI Plus 12.5mg + 1000mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 1666 Tablets 1666 Tablets	November 2018 November 2018 November 2018
EMPOLI Plus 12.5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 12.5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 5mg + 1000mg	Lab-01	2500 Tablets	January 2019

Tablet	Lab-02 Lab-03	2500 Tablets 2500 Tablets	January 2019 January 2019
EMPOLI Plus 5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	January 2019 January 2019 January 2019
EMPOLI Plus 5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	November 2018 November 2018 November 2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years TEFOD *(Tenofovir Alafenamide)* 25mg Tablets on 28th January, 2019 by following panel: 1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board 2. Mr. Aslam Shah, Member Registration Board. 3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. Metformin hydrochloride: The firm has submitted copy of GMP certificate for M/s Wanbury Limited, Andhra Pradesh, India. The certificate is valid till 05-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of invoice for the import of Empagliflozin (1kg) attested by AD (I&E) Karachi office dated 08-11-2018. Metformin hydrochloride: Firm has submitted copy of invoice for the import of metformin hydrochloride (1.5kg) attested by AD (I&E) Karachi office dated 25-05-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC

Shortcomings communicated	Response by the firm
Though you have submitted summary of batch analyses release results of the FPP manufacturer for relevant batches in quality overall summary, however it is not provided in relevant section of module 3	The firm has provided data of relevant section of Module 3.
Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product	The firm has submitted analytical method verification studies for both drug substances.

manufacturer for both compendial as well as noncompendial drug substance(s) (Empagliflozin and metformin hydrochloride) shall be submitted as per section 3.2.S.4-Control of drug substance	
How it is possible even in the presence of stress conditions, no degradation/impurities were observed in specificity parameter of analytical validation of finished product. Please justify your findings.	The firm has submitted that selectivity of method can be determined by following two methods • Spiking of impurities • Forced Degradation We performed both methods and no degradation has been observed due to high stability of these molecules.
The justification of specification(s) for non-pharmacopeial products must be provided.	The firm has submitted that we have developed in-house justification for inclusion of tests non-pharmacopoeial.
Details of reference standards needs to be submitted since details of metformin impurity A and metformin impurity F are submitted without mentioning API reference standard. In case of Empagliflozin, working standard of API has been procured. Justify the quantity of working standard procured will it be sufficient for complete test and analysis.	The firm has submitted that assay of Metformin hydrochloride performed by titrimetric method hence working standard not required. While for testing of finished product, reference standard is used to standardize the working standard. The firm has submitted justification for quantity of working standard procured for test and analysis. Amount of working standard procured is 125mg. 125mg is used for analysis of API. 125mg is used for standardization of in-house standard. 10mg working standard required for single analysis of finished product. No. of testing per strength is 6mg (60mg consumed). Total no. of testing per 6 strength is 36mg (360mg consumed).
Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	The firm has performed pharmaceutical equivalence of their test formulations with different strengths of Synjardy as below: • Synjardy 12.5/1000mg Tablets (Boehringer Ingelheim, Batch # 644963) • Synjardy 12.5/850mg Tablets (Boehringer Ingelheim, Batch # 544531) • Synjardy 12.5/500mg Tablets (Boehringer Ingelheim, Batch # 856310) • Synjardy 5/500mg Tablets (Boehringer Ingelheim, Batch # 856327) • Synjardy 5/850mg Tablets (Boehringer Ingelheim, Batch # 644574) • Synjardy 5/1000mg Tablets (Boehringer Ingelheim, Batch # 644648)
Though you have submitted brief summary of CDP with innovator in module 2, however the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed in relevant portion of module 3.	The firm has submitted performance of comparative dissolution test of their test formulations against innovator formulations in 3 different pH media i.e., 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8 for relevant section of module 3. The results show comparable dissolution with innovator's product

Decision: Registration Board decided to defer the cases for justification of using Titrimetric method alongwith performance of potentiometric end point for analysis of metformin API.

1846.	Name, address of Applicant / Marketing	M/s Global Pharmaceuticals (Pvt.) Ltd.

	Authorization Holder	Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28418 : 27-12-2019
	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..50mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 50mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)
	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and

		stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1847.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28419: 27-12-2019
	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 75mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..75mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 75mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)
	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in

		15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA

Manufacturer of API	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.		
API Lot No.	6TDL 0110318		
Description of Pack (Container closure system)	Alu-Alu Blister 1×10's		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
	Batch No.	Batch size	Manufacturing date
D-PAIN 50MG TABLET	T-001 T-002 T-003	1500 Tablets	09-2018
D-PAIN 75MG TABLET	T-001 T-002 T-003	1000 tablets	09-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#JX170001) for M/s Symed Labs Limited, India issued by Drug Control Administration, Government of Telangana, India. It was valid till 24-04-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Dissolution conditions of innovator as per Biopharmaceutics Review:
Apparatus: Type I (Basket apparatus)
Spindle rotation: 75 RPM
Medium: 0.1 M HCl
Medium volume: 900ml
Time: 45 min
Acceptance criteria: NLT 80% (Q) of the labelled amount of Tapentadol (as HCl) dissolved in 45 min

Sr. No.	Observations communicated	Response by the firm
1.	Submit Quality Overall Summary (QOS) needs to be submitted as per 293rd meeting of Registration Board.	The firm has submitted summarised information of drug substance and drug product as per 293rd meeting of Registration Board
2.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
3.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	The firm has submitted copy of GMP certificate however it is expired now.
4.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
5.	Summary of batch analyses release results of the drug product manufacturer for relevant batch needs to be submitted as per 2.3.S.4.4 (b).	Submitted
6.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Tapento IR 75mg tablet. Unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., 50mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.
7.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	Submitted.
8.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted data of relevant modules.

Decision: Registration Board decided as follows:

- **To defer registration application of D-Pain 50mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **To approve registration of D-Pain 75mg tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated**

	studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.	
1848.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4211: 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020
	The proposed proprietary name / brand name	Asprala 81mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated delayed release tablet contains: Aspirin……..81mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Film coated delayed release Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent and proton pump inhibitor
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablets 81mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 81mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Andra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Aspirin: The Firm has submitted 6months accelerated (40°C ± 2°C/75%± 5% RH) and 60months real time (30°C ± 2 °C/60%± 5% RH) stability study data of 3 batches. Omeprazole: The Firm has submitted 6months accelerated (40°C ± 2°C/75%± 5% RH) and 48months real time (30°C ± 2 °C/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1849.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4210 : 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020

	The proposed proprietary name / brand name	Asprala 325mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin……..325mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent (B01AC06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablets 325mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 325mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Aspirin:** The Firm has submitted 6months accelerated (40^{o}C ± 2 ^{o}C/75%± 5% RH) and 60months real time (30^{o}C ± 2 ^{o}C/60%± 5% RH) stability study data of 3 batches. **Omeprazole**: The Firm has submitted 6months accelerated (40^{o}C ± 2 ^{o}C/75%± 5% RH) and 48months real time (30^{o}C ± 2 ^{o}C/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor

		was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA			
Manufacturer of API	**Aspirin:** M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China **Omeprazole:** M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India		
API Lot No.	**Aspirin:** 171315 **Omeprazole:** OME/E-222/16		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	Batch size	Manufacturing date
ASPRALA 81MG/40MG TABLET	TT-001 TT-002 TT-003	13000 Tablets 13000 Tablets 13000 Tablets	06-2018 06-2018 06-2018
ASPRALA 325MG/40MG TABLET	TT-001 TT-002 TT-003	1500 Tablets 1500 Tablets 1500 Tablets	09-2019 09-2019 09-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Aspirin:** The firm has submitted copy of GMP certificate for M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China issued by Shangdong Food and Drug Administration. It is valid till 18-10-2022. **Omeprazole:** The firm has submitted copy of GMP certificate for M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India issued by Government of Telangana, Drugs Control administration. It was valid till 31-03-2017.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** Firm has submitted copy of commercial invoice specifying import of 5Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office dated 11-06-2018. **Omeprazole:** Firm has submitted copy of commercial invoice specifying import of 100Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office

		dated 13-05-2016.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Sr. No.	Observations communicated	Response by the firm
1.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Evidence of import of both APIs attested by AD (I&E), Islamabad is submitted
2.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	Valid GMP certificate for omeprazole is yet to be submitted.
3.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
4.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Yosprala 325mg/40mg tablet. But unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., Yosprala 81mg/40mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.
5.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	The firm has submitted analytical method validation studies.
6.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted details of drug substance and drug product as per 293rd meeting of Registration Board.

Decision: Registration Board decided as follows:

- **to defer registration application of Asprala 81mg/40mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **to approve registration of Asprala 325mg/40mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated**

studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.

Item No. : Agenda of Evaluator AD PEC-I

Item No. I: Registration Applications for Local Manufacturing of (Human) Drugs
a. New Cases

1850.	Name and address of manufacturer / Applicant	M/s Skim Pharmaceuticals 10/B value addition city Faisalabad
	Brand Name +Dosage Form + Strength	SKIFENAC Diclofenac Sodium 50mg sustain coated pellets
	Diary No. Date of R& I & fee	Each capsule contains: Diclofenac sodium sustained release pellets….50mg Source of Pellets: M/s Vision Pharmaceutical Islamabad
	Composition	Dy. No. 20075 dated 04-06-2018 Rs20,000/-Dated 04-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20,s capsule in Alu/PVC Blister & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac sodium 25mg & 50mg) gastro resistant **Tablet** by M/s Daxcel Pharma, MHRA Approved.
	Me-too Status	Lifdik 50mg capsule by M/s Goodmann, Reg No. 52586
	GMP Status	DML No. 000830 issue dated 03-12-2015 Panel recommended additional sections including Capsule (general) dated 19-01-2018
	Remarks of the Evaluator-I	The firm initially applied for Sustained Release Capsule and then it was revised as Enteric coated Capsule as per reference product and submitted fee Rs. 5,000/- vide challan number 0300788 dated 13/04/2020.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1851.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 1.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38171 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…….1.5mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's, Rs. 1000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 1.5mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. No. 079270
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.

	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
1852.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 9mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38174 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…9mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5D
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 4000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	• The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system. • Me too status could not be confirmed.
	Decision: Deferred for; • **Clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1853.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38173 dated 20-11-2018 Rs.20,000/- Dated
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…6mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 2700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Avega 6mg Tablets by M/s Biogen Pharma, Reg No. 080370
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.

	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
1854.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 3mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38172 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone……3mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 1700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets 1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 3mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. no. 079271
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
1855.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 50mg Tablets
	Diary No. Date of R& I & fee	Form-5D Dy.No 37929 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate……50mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D
	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 12,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	The firm has claimed In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). 06 month submit stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	
1856.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 100mg Tablets

	Diary No. Date of R& I & fee	Form-5D Dy.No 37928 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate…..…100mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D
	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 20,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	Stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	
1857.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 50mg/200mcg Tablets
	Diary No. Date of R& I & fee	Dy.No 38150 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 50 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Prostol Tablets by M/s Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore, Reg. No. 026839
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following; Each delayed release tablet contains: Diclofenac sodium…..50mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1858.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 75mg/200mcg Tablets

	Diary No. Date of R& I & fee	Dy.No 38151 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…..……75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 75 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Arsofin Tablets by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Reg. no. 48013
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following; Each delayed release tablet contains: Diclofenac sodium…..75mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1859.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Zipdone 40mg Capsule
	Diary No. Date of R& I & fee	Dy.No 38145 dated 19-11-2018 Rs.12,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….40mg
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 40mg capsule of M/s Nabiqasim Industries (Reg.#055651)
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The reference product contains Ziprasidone hydrochloride monohydtrate while the applied formulaiton contains Ziprasidone hydrochloride, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Ziprasidone Hydrochloride" in reference regulatory authorities/agencies which were adopted by	

	the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1860.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Applicant/Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Mol 1g/100ml Infusion (solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 37901 dated 16-11-2018 Rs.50,000/-
	Composition	Each 100ml Contains: Paracetamol…….1g
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paracetamol 10mg/ml Solution for Infusion (50ml vial, 100ml vial) by M/s Accord UK ltd, MHRA approved
	Me-too Status	Provas Infusion 10mg/ml by M/s Sami Pharma, Reg. No. 53223
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1861.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ferolas 100mg/5ml Injection
	Diary No. Date of R& I & fee	Dy.No 37900 dated 16-11-2018 Rs.50,000/-
	Composition	Each 5ml (ampoule) Contains: Iron as Iron Sucrose……100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General

		Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1862.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ton 8mg/4ml Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 37894 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each 4ml ampoule Contains: Ondansetron……8mg
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ondansetron 2 mg/ml (4mg/2ml & 8mg/4ml) Solution for Injection by M/s Hameln pharmaceuticals, MHRA Approved
	Me-too Status	Doston 8mg/4ml Injection by M/s Vision Pharmaceuticals, Kahuta Road, Islamabad. Reg. No. 081892
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1863.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Lac 30mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37893 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Ampoule (1ml) Contains: Ketorolac Tromethamine……..30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Toradol Injection 30mg/ampoule of 1ml by M/s Atnahs Pharma, UK (MHRA Approved)
	Me-too Status	Tromit Injection by M/s harm (Reg.# 049958)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1864.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Bufin 10mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37891 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (1ml) Contains: Nalbuphine HCl……10mg
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved.
	Me-too Status	Nalburax Injection by M/s Mediceena Pharma (Pvt) Ltd, Reg. No. 28830
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1865.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Penzol 40mg/Vial Injection (Lyophilized powder for solution for injection)

	Diary No. Date of R& I & fee	Dy.No 37892 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Pantoprazole as Sodium ……..40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	**PROTONIX IV** 40mg Powder (freeze dried) for Solution for Injection by M/s Wyeth Pharms, USFDA Approved.
	Me-too Status	Zonpep Injection 40mg IV by M/s Aulton Pharmaceuticals, Reg. No.
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1866.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-D3 5mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37895 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (ml) Contains: Cholecalciferol……..5mg (Eq. to approx. 200,000IU)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too Status	G-Cal 5mg Injection by M/s Glitz Pharmaceuticals, Reg. No. 66362
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.

	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1867.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Zole 40mg/Vial IV Infusion (Lyophilized Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37896 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Omeprazole as Sodium…..…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1868.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 1g Injection (Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37899 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Vancomycin as HCl…….1000mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	Vancocin Inection 1000mg of Eli Lilly Pakistan, Reg. No. 21081
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available.

		Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1869.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 500mg Injection
	Diary No. Date of R& I & fee	Dy.No 37898 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Vancomycin as Hcl….500mg (powder for injection)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	VANCIN I.M / I.V INJECTION 500MG by M/s CENTURY PHARMACEUTICAL (PVT) LTD, Reg. No. 22673
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1870.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Cycline 50mg Injection (Powder for solution)
	Diary No. Date of R& I & fee	Dy.No 37897 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Tigecycline……..50mg
	Pharmacological Group	Tetracycline derived antibiotic

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tigecycline 50 mg lyophilized cake or powder for solution for infusion by M/s Mylan (MHRA Approved)
	Me-too Status	Tygacil Injection 50mg by M/s Wyeth (Reg#045642)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1871.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ronic 3mg/3ml Injection
	Diary No. Date of R& I & fee	Dy.No 37903 dated 16-11-2018 Rs.50,000/-
	Composition	Each 3ml Contains: Ibandronic Acid…….3mg
	Pharmacological Group	Bone resorption inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ibandronate sodium 3mg/3ml vial by M/s Sun Pharm, USFDA Approved.
	Me-too Status	Ibro injection 3mg/3ml by M/s Regal Pharmaceuticals (Reg#082004)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1872.	**Name and address of manufacturer / Applicant**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi

	Contract manufacturing	**Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Esom IV 40mg Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Dy.No 37902 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
1873.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 4mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37921 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….4mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too Status	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
1874.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 8mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37926 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….8mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5

	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too Status	Recam Tablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
1875.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37922 dated 16-11-2018 Rs.20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008473 dated 24/01/2020.
	Decision: Deferred for; • **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
1876.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37925 dated 16-11-2018 Rs.20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	Anti-depressants
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008474 dated 24/01/2020.
	Decision: Deferred for;	

	• **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
1877.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Uniterf Fort 250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37923 dated 16-11-2018 Rs.20,000/-
	Composition	Each Tablet Contains: Terbinafine as HCL……250mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s NOVARTIS PHARMACEUTICALS UK LIMITED, MHRA Approved.
	Me-too Status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
1878.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Dianil 2mg Capsule
	Diary No. Date of R& I & fee	Dy.No 37924 dated 16-11-2018 Rs.20,000/-
	Composition	Each Capsule Contains: Loperamide Hydrochloride…2mg
	Pharmacological Group	***Antidiarrheals***
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6×10, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loperamide Capsules 2 mg by M/s Galpharm Healthcare Limited, MHRA Approved.
	Me-too Status	LOPAMIDE 2mg CA by M/s Medicaids, Reg. No. 11240
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
1879.	Name and address of manufacturer / Applicant	M/s Ciba Pharmaceutical private limitd, plot no. A-371, Nooriabad site industrial Area, Super highway Karachi.
	Brand Name +Dosage Form + Strength	LINO 500mg capsule
	Diary No. Date of R& I & fee	Dy.No.35276 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Lincomycin……..500mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2,6's×2, 5's×10, 10's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too Status	Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898
	GMP Status	According to the Last inspection report dated 07/02/2017, the firm is strictly following the GMP practice.

	Remarks of the Evaluator-I	The applied product is present in USP as well as BP. The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. Provide the proof of availability of Raman spectrometer if you want to claim USP specifications for the applied product. Provide evidence of approval of the applied product is Reference Regulatory Authorities approved by 275th meeting of Registration Board as the product is discontinued by USFDA and ANSM France.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1880.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16256 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82749
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1881.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16255 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…500gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82750
	GMP Status	Jinnah Pharma:

		The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1882.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 1gm IV Injection
	Diary No. Date of R& I & fee	Dy.No 16566 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm with L-Arginine Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
1883.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 500mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 16565 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride with L-Arginine 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained

		satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
1884.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 250mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16247 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone (250mg & 1gm) powder for solution for injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 250mg IM by M/s Caliph pharmaceuticals (Pvt.) Ltd, Reg. no. 82556
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1885.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 250mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16254 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…250gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA MHRA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the

		manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1886.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16250 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1887.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16249 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1888.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan

		Manufactured By: M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 1g IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16251 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1889.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 100mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16257 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…100mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1890.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 200mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16258 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019

	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…200mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30 ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1891.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 16259 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Capsule Contains: Cefixime as Trihydrate….400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1892.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mg
	Pharmacological Group	
	Type of Form	Form-5

	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1893.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16253 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…1gm Cefoperazone as Sodium…1gm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015 273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1894.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection

	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
1895.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi
	Brand Name +Dosage Form + Strength	Diraximin 200mg Tab
	Diary No. Date of R& I & fee	Dy.No 266 dated 09/11/2016 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each Film Coated Tablet Contains: Rifaximin……200mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 200mg film-coated tablets, for oral use. **USFDA** approved
	Me-too Status	Nimixa 200mg Tablet film-coated. Reg. No. 70734
	GMP Status	The panel dated 04-10-2019 recommends for renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1896.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	NS+20K Infusion 100ml
	Diary No. Date of R& I & fee	Dy.No 71 dated 10/09/2013 Rs.50,000 Dated 10-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each ml contains: Sodium chloride……..9mg Potassium chloride…..150mg
	Pharmacological Group	Electrolytes
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack Size & Demanded Price	100ml vial(as per SRO)
	Approval Status of Product in Reference Regulatory Authorities	Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion – BP by M/s Baxter healthcare, MHRA Approved. (strength is not same)
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	The applied product does not contain the same strength of potassium chloride as the product contains approved by reference regulatory authorities (RRAs). Provide evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revise the formulation along with the applicable fee. evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for; • **Evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1897.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Acbenzo 4% w/w Cream
	Diary No. Date of R& I & fee	Dy.No 1399 dated 13/01/2017 Rs.20,000 Dated 05-01-2017 **Duplicate file** The file is received from R-I Section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 100g cream contains: Benzoyl Peroxide….4g
	Pharmacological Group	Anti infective
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Brevoxyl 4% Cream by M/s GSK consumer healthcare, MHRA Approved.
	Me-too Status	Prayzid Cream 4% cream by M/s Pray Pharma, Reg. No. 72415
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1898.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colonclean Syrup
	Diary No. Date of R& I & fee	Dy.No 69 dated 10/09/2013 Rs.50,000 Dated 04-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 5ml contains: Sodium potassium monobasic….2.4g Potassium dibasic…….0.9g
	Pharmacological Group	Purgative
	Type of Form	Form-5D
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for; • **Evidence of approval of the same formulation in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1899.	Name and address of manufacturer / Applicant	**Manufacturer:** M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore **Applicant:** M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd , Lahore
	Brand Name +Dosage Form + Strength	Cewel Dry suspension 100mg/5ml
	Diary No. Date of R& I & fee	Dy.No 5800 dated 05/07/2010 Rs.8,000 Dated 03-07-2010 Differential fee 42,000/- dated 22/01/2015 **Duplicate file** The application is received from R-II section vide letter no. F.1-11/2019-Reg-II dated 24/12/2019.
	Composition	Each 5ml reconstituted suspension contains: Cefixime Trihydrate equivalent to Cefixime…100mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Harmann Pharma: **Decision of 272st Meeting of CLB:** I- Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections. a- Sterile Section-I (General Injection) b- Sterile Section-III (Hormonal Injection) II- Regularize the layout plan of Hormonal Section, as per recommendations of the panel in the reort dated 13-06-2019 & 08-10-2019. Synchro Pharma: Inspection report dated 30/06/2020. "it was observed that firm had rectified most of the shortcomings and for remaining shortcomings fir was advised to submit CAPA within stipulated time and re-inspection will be conducted accordingly".
	Remarks of the Evaluator.	Copy of agreement is attached The applicant has stated that there are no products being manufactured on contract. M/s Harmann Pharma has 7 approved sections.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder suspension cephalosporin section" for applied formulation.	

1900.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nystanil oral solution 100,000 units/ml
	Diary No. Date of R& I & fee	Dy.No 9908 dated 25/07/2017 Rs.20,000 **Duplicate dossier** The application is received from R-I section vide letter no. F.1-2/2019-Reg-I dated 01/01/2020.
	Composition	Each ml contains: Nystatin……100,000 units
	Pharmacological Group	antimycotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nystatin Oral Suspension BP by M/s Sandoz ltd, MHRA approved.
	Me-too Status	Nystrin Suspension 100,000/- per ml by M/s Harmann Pharma, Reg. No. 28119
	GMP Status	09-10-2018 Routine GMP Inspection "overall GMP compliance level is rated as good." Liquid syrup section is available.
	Remarks of the Evaluator.	• The applied product is Oral Solution while the approved product is reference country is Oral Suspension, provide the evidence of approval in reference regulatory authorities as approved by Registration Board in 275th meeting or otherwise submit revised formulation as per reference product along with the submission of applicable fee. • The firm has revised formulation the formulation from Oral Solution to Oral Suspension as per the reference product and submitted fee (Rs. 5,000/- challan number 1976772 dated 30/07/2020 + Rs. 15,000/- challan number 2034651 dated 09/09/2020).
	Decision: Approved with the following details; **Brand name:** **Nystanil oral suspension 100,000 units/ml** **Label Claim:** **Each ml contains:** **Nystatin……100,000 units** **Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.**	
1901.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra Injection 500mg/5ml
	Diary No. Date of R& I & fee	Dy.No 14122 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each 5ml contains: Levetiracetam…500mg
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 325/- per ampoule
	Approval Status of Product in Reference Regulatory Authorities	KEPPRA 500mg/5ml Injection of USFDA approved

	Me-too Status	Lumark Injection M/s Searle Pak
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Injectable section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1902.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra 100mg/ml Oral solution
	Diary No. Date of R& I & fee	Dy.No 14123 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each ml contains: Levetiracetam…100mg
	Pharmacological Group	antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs 432/- per 60ml, Rs. 720/- per 120ml
	Approval Status of Product in Reference Regulatory Authorities	LEVETIRACETAM (Levetiracetam100mg/ml) solution; oral By M/s TARO. USFDA Approved.
	Me-too Status	Levotam Oral solution 100mg/ml By M/s Platinum, Karachi. (Reg.# 070837)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Oral liquid section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1903.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Oxepin Capsules 3/25mg
	Diary No. Date of R& I & fee	Dy.No 14124 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each capsule contains: Olanzapine……..3mg Fluoxetine as HCl…….25mg
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 20/- per capsule
	Approval Status of Product in Reference Regulatory Authorities	Symbyax 3mg/25 mg Capsules by Ms/ Eli Lilly, USA (USFDA approved).
	Me-too Status	Olanco Capsules by Genome Pharma. (Reg. # 079388)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Capsule section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1904.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore.

		Manufacturer: M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Esomark 40mg Infusion Lyophilized powder for infusion
	Diary No. Date of R& I & fee	Dy.No 3083 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Esomeprazole as Sodium…..400mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.
	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1905.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore. **Manufacturer:** M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Biomep 40mg Infusion Lyophilized powder for solution
	Diary No. Date of R& I & fee	Dy.No 3084 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.

	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1906.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Phlocin Injection
	Diary No. Date of R& I & fee	Dy.No 485 dated 21-03-2014 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II.
	Composition	Each 4ml ampoule contains: Phloroglucinol hydrate…….40mg Trimethylphloroglucinol…..0.04mg
	Pharmacological Group	Antispasmodic.
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too Status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP Status	GMP certificate issued on 10/12/2018 on the basis of inspection conducted on 08/11/2018. Liquid injectable section available
	Remarks of the Evaluator-I	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1907.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Florlina Plus powder
	Diary No. Date of R& I & fee	Dy.No 12 dated 01-07-2015 Rs.20,000 Dated 30-06-2015 **Duplicate file**
	Composition	Each 100g contains: Neomycin Sulphate…….15gm Florfenicol……..10gm Oxytetracycline Hcl……..30gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	100gm, 200gm 500gm, 1kg, price decontrolled
	Me-too Status	NEOXFLOR ORAL POWDER (150mg, 100mg 300mm per gram) by M/s Baariq Pharma, Reg. No. 088638
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Deferred for updated status of GMP from QA & LT division.	
1908.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Enflox-c plus liquid
	Diary No. Date of R& I & fee	Dy. No 13 dated 01-07-2015 Rs.20,000 Dated 30-06-2015 **Duplicate file**
	Composition	Each 100ml contains:

		Enrofloxacin……..…10mg Cloistin sulphate…….100mg Amantadine HCl…..…300gm
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished Product Specification	Inhouse
	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Evidence of GMP is required.
	Remarks of the Evaluator.	
	Decision: Deferred for following: **Updated status of GMP from QA & LT division.** **Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name & name of firm.**	
1909.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Colate powder for solution for injection
	Diary No. Date of R& I & fee	Dy.No 39066 dated 29-11-2018 Rs.20,000 Dated 27-11-2018 (Duplicate file)
	Composition	Each vial contains; Colistimethate sodium…….……1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Date of inspection 10/04/2019, acceptable level of cGMP compliance
	Remarks of the Evaluator-I	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1910.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Janumet tablet
	Diary No. Date of R& I & fee	Dy.No 28 dated 01-07-2014 Rs.20,000 Dated 01-07-2014 **Duplicate file**
	Composition	Each tablet contains: Sitagliptin……..50mg Metformin HCl……..500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 1,500/- per pack of 2×7's
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	The firm has submitted the correct composition as per the reference product given in the following without submission of any fee. Each film coated tablet contains:

		Sitagliptin as phosphate monohydrate……..50mg Metformin HCl…….500mg
	Remarks of the Evaluator.	
	Decision: Deferred for submission of requisite fee for revision of formulation as per reference product.	
1911.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Relspasm Injection 4mg/2ml
	Diary No. Date of R& I & fee	Dy.No 749 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(02/06/2011)+12,000(14/01/2015) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each ml contains: Thiocolchicooside……2mg
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis (ANSM France)
	Me-too Status	Myolax 2mg Injection (4mg/2ml ampoule) by M/s Saffron, Reg. no. 60355
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019. Liquid injectable section is available.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1912.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Derams Injection 500mg IV Powder for solution
	Diary No. Date of R& I & fee	Dy.No 748 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(03/06/2011)+12,000(16/12/2014) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each vial contains: Thiopental sodium…500mg (as a mixture of Thiopental sodium and sodium carbonate)
	Pharmacological Group	Genera anesthetic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Thiopental Sodium 500mg Powder for Solution for Injection by M/s Kyova kirin ltd, MHRA Approved.
	Me-too Status	M-Pentone 500mg Injection by M/s Mediate, Reg. No. 61946
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019.

		Dry powder injectable section is available.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification of method of manufacturing of the applied product whether via lyophilization or dry powder filling alongwith reference / innovator's product manufacturing method.	
1913.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunate injection 250mg Powder for injection
	Diary No. Date of R& I & fee	Dy.No 166 dated 03-11-2016 Rs.20,000 Dated 02-11-2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone as sodium succinate……250mg
	Pharmacological Group	Glucocorticoid-Minerolcorticoid
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Hydrocortisone as sodium succinate Injection-USFDA
	Me-too Status	Solu-cortef by Pfizer Pharma
	GMP Status	Date of inspection 11-02-2019, good level of GMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of required manufacturing facility/section approval from Licensing division.	
1914.	Name and address of manufacturer / Applicant	M/s Zakfas pharmaceutical pvt Ltd. 12-Km, bosan raod, multan.
	Brand Name +Dosage Form + Strength	Gen-One topical spray
	Diary No. Date of R& I & fee	y.No 546 dated 09-06-2016 Rs.50,000 Dated 09-06-2016
	Composition	Each ml contains: Gentamicin as sulphate……0.57mg Betamethasone as valerate……0.284mg
	Pharmacological Group	Antibiotic/corticosteroid
	Type of Form	Form-5D
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Me-too Status	Could not be confirmed
	GMP Status	
	Remarks of the Evaluator.	Section approval letter. GMP inspection report International availability. Stability required.
	Decision: Deferred for following; • **Required manufacturing facility/section approval from Licensing Division.** • **Latest GMP inspection report.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1915.	Name and address of manufacturer / Applicant	M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Exelor 50mg tablet
	Diary No. Date of R& I & fee	Dy.No 10146 dated 26-07-2017 Rs.20,000 Dated 24-07-2017
	Composition	Each film coat tablet contains: Vildagliptin……..50mg
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5

	Finished Product Specification	Manufacturer
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GALVUS (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pvt Ltd. TGA approved
	Me-too Status	V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908)
	GMP Status	Inspection date, 27/12/2018, the firm is working in compliance to GMP standards.
	Remarks of the Evaluator-I	The firm has revised the formulation from Film Coated to Uncoated Tablet with submission of Rs. 5000/- challan no. 1938304 dated 08/12/2019 as per the reference product given in the following; Each Tablet contains: Vildagliptin……..50mg
	Decision: Approved with innovator's specifications	
1916.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Azocin 250mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 (slip no. **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……250mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 150/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269
	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1917.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Azocin 500mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……500mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack Size & Demanded Price	Rs. 275/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269
	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
1918.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Global Pharmaceuticals, Plot No. 204-205, Industrial Triangle, Kahuta road, Islamabad. **Manufacturer:** M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Glonate Injection 250mg
	Diary No. Date of R& I & fee	Dy.No 166 dated 03/11/2016 Rs.20,000/- dated 02/11/2016 + Rs. 30,000/- 10/11/2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone sodium succinate…….250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Global Pharma: Inspection date 26/12/2018, panel recommended renewal of DML. Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	Clarification is required since the product approved in reference country contains "Hydrocortisone as sodium succinate 250" while the label claim of the applied product is "Hydrocortisone sodium succinate 250mg". Form 5 is submitted by the manufacturer while it should be submitted by the applicant. Detail of number of products being manufactured for M/s Global Pharmaceuticals is required. Provide number of approved sections of M/s Global Pharmaceuticals.
	Decision: Deferred for submission of the followings; • **Evidence of approval of applied formulation containing "Hydrocortisone sodium succinate 250mg" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Form 5 is submitted by the manufacturer while it should be submitted by the applicant.** • **Detail of number of products being manufactured for M/s Global Pharmaceuticals is required.** • **Provide number of approved sections of M/s Global Pharmaceuticals.**	
1919.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.

	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……1000mgs
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/1000 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53404
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1920.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40987 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1921.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Demant 5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…5mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Torrent 5mg Film-coated Tablets by M/s Torrent Pharma (UK) Ltd, MHRA Approved.
	Me-too Status	Afdol 5mg Tablets by M/s AGP (R # 047166)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1922.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.

	Brand Name +Dosage Form + Strength	Demant 10mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41017 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…10mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Accord (5mg, 10mg, 15mg, 20mg) film-coated tablets by M/s Accord, MHRA Approved.
	Me-too Status	Afdol 10mg Tablets by M/s AGP (R # 044429)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1923.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 250mg
	Diary No. Date of R& I & fee	Dy. No. 41005 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….250mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote 250mg Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 250mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024464)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1924.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 500mg
	Diary No. Date of R& I & fee	Dy. No. 41006 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….500mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote (250mg, 500mg) Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 500mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024465)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1925.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 20mg

	Diary No. Date of R& I & fee	Dy. No. 40997 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……20mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 20mg tablet by M/s Getz Pharma, Reg. No. 33430
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovatpr's specifications.	
1926.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 40mg
	Diary No. Date of R& I & fee	Dy. No. 40998 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 40mg tablet by M/s Getz Pharma, Reg. No. 33431
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1927.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Omefit 40mg Capsules
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Omeprazole enteric coated pellets…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Losec Capsule (20mg, 40mg) by M/s Astra Zaneca (MHRA Approved)
	Me-too Status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	Source= Vision Pharma,
	Decision: Approved.	
1928.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 25mg
	Diary No. Date of R& I & fee	Dy. No. 40989 dated 06/12/2018 Fee Rs. 20,000/-

	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1929.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 12.5mg
	Diary No. Date of R& I & fee	Dy. No. 40990 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1930.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 10mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41004 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amlodipine and Olmesartan Medoxomil 10/20mg film coated tablet by M/s Torrent USFDA Approved.
	Me-too Status	Omsana-AM 10/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58559
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1931.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals,

		Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 5mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41003 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 5/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58557
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1932.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metlipsy 800mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41000 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Piracetam 800mg film-coated tablet by M/s USB Pharma, MHRA approved
	Me-too Status	Nootropil Tablet 800mg by M/s GSK Reg. No. 82277
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
1933.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mydin 10mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41024 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each tablet contains: Loratadine……..10mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Roletra 10 mg Tablets by M/s Ranbaxy (UK) Limited. MHRA approved
	Me-too Status	Senergy OD 10mg tablet by M/s Highnoon (Reg.#017672)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

1934.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 20mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.….20mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 20mg tablet by M/s ' Highnoon Laboratories, Reg. no. 48371
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1935.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 40mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.….40mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Aurora Tablets 40mg by M/s Ferozsons Laboratories, Reg. no. 54747
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1936.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Relaxer tablet 4mg
	Diary No. Date of R& I & fee	Dy. No. 41019 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each uncoated tablet contains: Thiocolchicoside ……4mg
	Pharmacological Group	Anti Parkinson, neuralgia
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	THIOCOLCHICOSIDE EG 4 mg, scored tablet. **ANSM France** approved
	Me-too Status	Myolax Tablets 4mg by M/s Reko Pharma Reg. No. 74170
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

1937.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Konaz cream 2% w/w
	Diary No. Date of R& I & fee	Dy. No. 41023 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each gram contains: Ketoconazole… 20mg (2% w/w)
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Daktarin Gold 2% Cream by M/s McNeil Products Limited, MHRA Approved.
	Me-too Status	Bizrole Cream 2 % by M/s Searle IV Solutions (Pvt.) Ltd, Reg. No. 78620
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
1938.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Binaf Cream 1% w/w
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Gram of cream contains: Terbinafine as HCl ……..10mg (1%)
	Pharmacological Group	Anti fungal
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Terbinafine HCl 1% cream by M/s Taro, USFDA Approved
	Me-too Status	Terbisan caream 1% by M/s Elko organization (PvT) ltd. Reg # 27076
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
1939.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metacid Oral Suspension
	Diary No. Date of R& I & fee	Dy. No. 41030 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each 5ml contains: Aluminium hydroxide…….215mg Magnesium hydroxide…….80mg Simethicone…….25mg
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be verified

	Me-too Status	Simecrol Suspension by M/s Hicon Pharmaceuticals (Reg.#041458)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

b. Deferred Cases (Local manufacturing) Human

1940.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi. (8 sections)
	Brand Name +Dosage Form + Strength	MAXI Eye Drops (Opthalmic Solution)
	Diary No. Date of R& I & fee	Dy.No.35273 dated 12/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Moxifloxacin as HCl…….5mg
	Pharmacological Group	Anti-infective/Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MOXIVIG 0.5%w/v eye drops, solution by M/s Novartis Pharmaceuticals UK Limited, MHRA Approved.
	Me-too Status	Ocumox-D Eye Drops by M/s Remington Pharmaceutical Industries, Reg No. 67888
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution and submitted Rs. 5000/- vide Callan number 1909480 dated 29/11/2019. The applicant has 08 sections. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035976 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Moxifloxacin as HCl…….5mg (Opthalmic solution) **Decision: Approved.**	
1941.	**deleted**	
1942.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	KATS sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35269 dated 24/10/2018 PKR 50,000/-

	Composition	Each ml of suspension contains: Ketorolac Trimethamine……5mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	MFG
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketorolac trometamol 0.5% w/v eye drops, solution by M/s Brown & Burk UK Ltd,MHRA Approved.
	Me-too Status	Ketro 0.5% Eye Drops by Ms/ Vega Pharmaceuticals (Pvt) Ltd, Reg No. 54030
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has claimed In-House manufacturing specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The firm has revised the formulation of the applied product from ophthalmic suspension to ophthalmic solution and submitted Rs. 5000/- vide challan number 1909484 dated 29/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035977 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Ketorolac Tromethamine……5mg (Opthalmic solution) **Decision: Approved with innovator's specifications.**	
1943.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	PATLERG sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35270 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml contains: Olopatadine as HCl……..1mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Olopatadine 1 mg/ml Eye drops, Solution by M/s Brown & Burk UK Ltd, MHRA Approved.
	Me-too Status	Zolopat 0.5% eye drops by Ms/ Remington Pharmaceutical Industries**,** Reg. No. 065991
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909483 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.

	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035978 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..1mg (Opthalmic solution) **Decision: Approved.**	
1944.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	PATLERG FORTE Sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35271 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Olopatadine as HCl……..2mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	OLOPATADINE HYDROCHLORIDE 0.2% opthalmic solution by M/s CIPLA, USFDA Approved.
	Me-too Status	Plop Forte Ophthalmic solution 2mg/ml by M/s Genix Pharma, Reg. No. 73680
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909482 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035979 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..2mg (Opthalmic solution) **Decision: Approved.**	
1945.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Omezole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40951 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial vontains: Omeprazole as Sodium…40mg (Lyophilized powder)
	Pharmacological Group	PPI
	Type of Form	Form 5

	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1946.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Lorno 8mg for Injection IV/IM
	Diary No. Date of R& I & fee	Dy. No. 43539 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial contains: Lornoxicam……8mg (Lyopilized powder)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too Status	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for following: a. Confirmation whether application is by lyophilization process or powder filling. b. Registration status of M/s Biolab for same formulation. **Submission of the firm:**	

	a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1947.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Esozole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40952 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg (Lyophilized powder of Esomeprazole sodium)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1948.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awablock 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole……40mg"
	Diary No. Date of R& I & fee	Dy. No 11728 dated 30-03-2018 Rs.50,000/- Dated 29-03-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi, (Reg#050651)
	GMP status	Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. The firm has applied for Esomeprazole 40mg while reference product contains Esomeprazole as sodium 40mg. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1949.	Name and address of manufacturer / Applicant	Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad Manufactured by Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	EPI 40mg Injection
	Composition	Each vial contain: Esomeprazole (as Sodium).....40mg
	Diary No. Date of R& I & fee	Dy. No. 5781 Date:29-08-2016 Rs. 50,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Nexium I.V. 40mg of (MHRA approved)
	Me-too status (with strength and dosage form)	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance
	Previous Remarks of the Evaluator [IV]	Contract agreement attached Number of already registred contract manufactured products: Nil
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products **(M-282)**
	Evaluation by PEC	Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin)

		• Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision of 295th meeting: Registration Board deferred the case for confirmation of dry powder vial filling facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1950.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winlor 8mg Injection
	Composition	Each Vial Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 1153 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved
	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for following: • confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise. • DML status of M/s Alen **Submission by the firm:** a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic (Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. c. The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for following: **Confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.** **Confirmation of DML status of M/s Alen Pharmaceuticals pvt. Ltd, Risalpur.**	
1951.	**Name and address of manufacturer / Applicant**	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	BIMEP 40MG INJECTION IV

	Composition	Each vial contains: Omeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19491, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
1952.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	NULOC 40MG INJECTION IV
	Composition	Each vial contains: Esomeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19492, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Nexium IV 40mg powder for solution for injection of AstraZeneca, UK (MHRA)
	Me-too status	Somezol Injection of Bosch, Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Firm's response	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for

		lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
1953.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winrose Injection 100mg/5ml
	Composition	Each ampoule contains: Iron sucrose…100mg
	Diary No. Date of R & I & fee	Dy. No. 1152 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• Revise the label claim and salt from in line with the reference product along with submission of applicable fee. • The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
1954.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zolid 600mg/300ml Infusion
	Composition	Each Vial Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 1151 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020.

		Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	D Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
1955.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Locrim 400mg Infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 1154; 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
1956.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Esofil 40mg IV Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 38082 dated 19-11-2018 Rs.50,000/- Dated 16-11-2018

	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic(Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
1957.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad. **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Noctis 40mg IV Injection (Lyophilized powder for solution)
	Diary No. Date of R& I & fee	Dy.No 38081 dated 19-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Omeprazole as Sodium……40mg
	Pharmacological Group	PPI
		Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	

	Submission by the firm: The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic (Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
1958.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-Penta injection IV
	Diary No. Date of R& I & fee	Dy. NO 633, 20-3-15, 50,000/-
	Composition	Each vial contains:- Pantoprazole lyophilized…….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Protonix by Wyeth (USFDA)
	Me-too status	Neege by Sami pharma
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1959.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Albepra injection

	Diary No. Date of R& I & fee	Dy. NO 636, 20-3-15, 50,000/-
	Composition	Each vial contains:- Omeprazole sodium equivalent to omeprazole….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of Sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1960.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-EZO injection
	Diary No. Date of R& I & fee	Dy. NO 634, 20-3-15, 50,000/-
	Composition	Each vial contains:- Esomeprazole (as Sodium)……..40mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished Product Specification	As per innovator
	Pack size & Demanded Price	1's As Per SRO

	Approval status of product in Reference Regulatory Authorities.	Esomeprazole of Consilient pharma (MHRA)
	Me-too status	Brince of ACE
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
1961.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Clida Gel 1%
	Diary No. Date of R& I & fee	Dy.No 43888 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Clindamycin Phospate eq to Clindamycin…1% 10mg
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	RESIDERM 1%w/w GEL by M/s Crawford Healthcare Limited (MHRA Approved)
	Me-too Status	Clindacin Gel 1%w/w by M/s Sante (Reg#067485)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	

1962.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sisul Cream, 1%
	Diary No. Date of R& I & fee	Dy.No 43886 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Silver Sulfadiazine…1% (w/w)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Silvadene Cream 1% of USFDA approved
	Me-too Status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	
1963.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jusidic Eye Drops
	Diary No. Date of R& I & fee	Dy.No 43887 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gm contains: Fusidic acid…1%
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucithalmic 1%w/w viscous eye drops, MHRA Approved
	Me-too Status	Fusitek Eye Drops 1% by M/s Invotek Pharma, Reg. No. 26957
	GMP Status	Same as stated above Ear/Eye Drops (General/Steroidal) section approved.
	Remarks of the Evaluator.	The firm has revised the formulation from 1% w/v to 1% w/w without submission of fee.
	Decision of 293rd meeting: Deferred for submission of applicable fee for revision of formulation. Submission by the firm: The firm has submitted the fee Rs. 5,000/- vide challan number 1932506 dated 12/08/2020. **Decision: Approved.**	
1964.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hisone 250mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42385 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Hydrocortisone sodium Succinate eq to Hydrocortisone…250mg
	Pharmacological Group	Corticosteroid

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision of 295th meeting: Deferred for confirmation of section in M/s Rotex Pharma Pvt Ltd . Submission by the firm: The applicant has submitted Sterile Dry Powder Vial (Steroid) Section approval letter No. F.1-53/2003-Lic(Vol-I) dated 4th Dec, 2018 issued by Secretary Licensing Board. **Decision: Aprproved.**	
1965.	Name and address of Applicant	M/s Excel Healthcare Laboratories Pvt Ltd. House. D#122, Block 4 Federal B Area Karachi, Pakistan.
	Name and address of manufacturer	M/s Pharma vision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey
	Marketing authorization holder	M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey
	Exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 35530 Dated 25-10-2018
	Fee including differential fee	Rs. 50,000/- Dated 25-10-2018
	Brand Name +Dosage Form + Strength	Gembag 100mg/2ml Solution for IM Injection
	Composition	Each ampoule contains: Iron III hydroxide polymaltose complex….333.33mg (Eq. to 100mg elemental iron)
	Finished Product Specification	Firm claim In-House specification
	Pharmacological Group	Parenteral iron preparation
	Shelf life	24 Months
	Pack size & Demanded Price	2ml glass ampoule & As per SRO
	International availability	FERRUM H iron 100mg/2mL (as polymaltose) injection ampoule (TGA Australia)
	Me-too status	Reg No. 041029by M/s Schazo Pharma Lab.
	Stability studies	Firm has submitted long term (24 months) at 30+2ºC, 65+5%RH & accelerated (06 months) stability data at 40+ 2ºC, 75+ 5% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 2018/1000) issued on 07-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Pharmavision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey. This certificate is valid until 17-03-2020. • Original product specific Sole agency agreement dated 23rd March 2018 of importer M/s Excel Healthcare Laboratories Pvt Ltd with Product License Holder M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of differential fee i.e. 50,000/- since the applied formulation is already registered by DRAP. Evaluation by PEC: The firm has submitted differential fee Rs. 50,000/- vide challan number 2001025 dated 13/08/2020.	

	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm will provide valid CoPP for further processing of case.	
1966.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Laderfex-D Tablet 60/12 0
	Composition	Each tablet contains:- Fexofendine HCl…….60mg Pseudoephedrine HCl……..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10954 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D Tab of Sanofi Aventis, USFDA
	Me-too status	Fenadrin D Tablet of Noa Hemis (Reg#042352)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
1967.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Hirafen-Plus Tablet 200mg/30mg
	Composition	Each film coated tablet contains:- Ibuprofen……200mg Pseudoephedrine HCl……..30mg
	Diary No. Date of R& I & fee	Dy. No 10824 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	NSAID/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Advil Cold and Sinus of Pfizer, USFDA
	Me-too status	Rovinac Tablets of Rock Pharma (Reg# 064206)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. **Decision: Approved with innovator's sepcifications.**	
1968.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi

	Brand Name +Dosage Form + Strength	Slorit-D Tablet 2.5/120
	Composition	Each tablet contains:- Desloratadine……2.5mg Pseudoephedrine Sulfate…..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10953 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067246)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
1969.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Slorit-D Tablet 5/240
	Composition	Each tablet contains:- Desloratadine……5mg Pseudoephedrine Sulfate…..240mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10955 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067247)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
1970.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals, 19 Km G.T. road, Kalashah Kaku, Lahore.
	Brand Name +Dosage Form + Strength	COLIMETH Dry powder for Injection
	Diary No. Date of R& I & fee	Dy.No. 35528 dated 25/10/2018 PKR 20,000/-

	Composition	Each vial contains; Colistimethate Sodium…….1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Last inspection report dated 20/09/2017 concludes the overall condition of the firm as satisfactory.
	Remarks of the Evaluator.	
	Decision of 289th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Submission by the firm: The firm has submitted that lyophilized raw material will be imported and filled in General Powder Filling section. The firm has been granted Dry Powder Injection (General) Section vide section approval letter No. F.1-63/84-Lic (Vol-III-A) dated 3rd October, 2019. **Decision: Approved.**	
1971.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR-300 Tablets
	Diary No. Date of R& I & fee	Dy.No 41447 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Extended Release Tablet Contains: Quetiapine as Fumarate…300mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm: The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 300mg Tablet of M/s Hilton Pharma , Reg No. 76087. **Decision: Approved.**	
1972.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR 150 Tablets
	Diary No. Date of R& I & fee	Dy.No 41448 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…150mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm: The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 150mg Tablet of M/s Hilton Pharma , Reg No. 067501. **Decision: Approved.**	

1973.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Ceftax 250mg Injection
	Composition	Each vial contains: Cefotaxime (as cefotaxime sodium)……. 250mg
	Diary No. Date of R& I & fee	Dy. No. 10774 dated 05/03/2019 R. 20,000/- dated 05/03/2019
	Pharmacological Group	Antiobiotic
	Type of Form	Form 5
	Finished Product Specification	B.P
	Pack size & Demanded Price	1's, as per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Cefon injection 250mg (vial) of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision pf 291st meeting: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by CIMA Spain and the reference provided by the firm has been verified and given in the following; Caefotaxima Normon 250mg powder and solvent for injectable IV EFG (Status: Marketed). Each vial contains: Cefotaxime as sodium…… 250mg The website was accessed on 29/06/2020. https://cima.aemps.es/cima/publico/lista.html **Decision: Approved.**	

1974.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	CLOBAM Tablet 10mg
	Composition	Each tablet contains: Clobazam……..10mg
	Diary No. Date of R & I & Fee	Dy No.12236 dated 06-03-2019 ; Rs.20,000 06/03/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	B.P Specs
	Pack Size & Demanded Price	3×10's Price as per SRO

	Approval Status of Product in Reference Regulatory Authorities	Onfi tablet (10mg, 20mg) by M/s Lundbecl Pharms LLC, USFDA Approved
	Me - too Status	Frisium tablet 10mg Reg No 2692
	G. M. P. Status	Inspection report dated 22/02/2019 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for scientific justification of overage present in the applied formulation.	
	Evluation by PEC: The firm has submitted revised formulation along with the master formula omitting the overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
1975.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	DINOP – E2 Tablet 3mg
	Composition	Each tablet contains: Dinoprostone…….. 3mg
	Diary No. Date of R & I & Fee	Dy. No.6511 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Prostaglandin Analog
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Prostin E2 vaginal tablet by M/s Pfizer MHRA Approved
	Me - too Status	Prostin E-2 by Pfizer vaginal tablets (Reg. No. 009821)
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The firm has applied for **oral tablet** while the product approved in reference authority is **Vaginal Tablet**.
	Decision of 293rd meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Evaluation by PEC: The firm has stated that it was a typographical error and Oral Tablet was written instead of Vaginal Tablet. The evidence of approval in reference authority and me-too status have already been verified as Vaginal tablet. Following is the correct label claim submitted by the firm. The firm has no tsubmitted any fee. Each vaginal tablet contains: Dinoprostone…….. 3mg **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
1976.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	TENIL Tablet 6mg
	Composition	Each Tablet Contains: Bromazepam……6mg
	Diary No. Date of R & I & Fee	Dy. No.6506 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5

	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Apo-bromazepam tablet (1.5mg, 3mg, 6mg) by M/s Apotex Inc. Health Canada Approved
	Me - too Status	Yazd 6mg Tablet By M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65693
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation without overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
1977.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.25mg
	Composition	Each Tablet Contains: Alprazolam……. 0.25mg
	Diary No. Date of R & I & Fee	Dy No.6501 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.25mg by M/s Pfizer, MHRA Approved
	Me - too Status	Lydia 0.25mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65697
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
1978.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.5mg
	Composition	Each Tablet Contains: Alprazolam……. 0.5mg
	Diary No. Date of R & I & Fee	Dy No.6502 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.50mg by M/s Pfizer, MHRA Approved

	Me - too Status	Lydia 0.50mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65705
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
1979.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 1 mg
	Composition	Each Tablet Contains: Alprazolam……. 1 mg
	Diary No. Date of R & I & Fee	Dy No.6503 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 1.0mg by M/s Pharmacia and Upjohns, USFDA Approved
	Me - too Status	Lydia 1.0mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65699
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	

1980.	**Name and address of manufacturer / Applicant**	**M/s Ciba Pharmaceutical private limitd, plot no.** A-371, Nooriabad site industrial Area, Super highway Karachi.
	Brand Name +Dosage Form + Strength	VOXY 100mg capsule
	Diary No. Date of R& I & fee	Dy.No.35275 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Doxycycline as hyclate…….100mg
	Pharmacological Group	tetracycline
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2, 5's×6, 5's×10, 5's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Doxycycline 100mg Capsules by M/s Kent Pharmaceuticals Ltd, MHRA Approved.
	Me-too Status	Medox Capsule 100mg by M/s Maxitech, Reg. No. 84781
	GMP Status	GMP certificate has been issued on 20/08/2019 based on inspection conducted on 07/08/2019.
	Remarks of the Evaluator.	The firm has revised the formulation from doxycycline monohydrate to Doxycycline as

		hyclate as per the composition of the reference product **without submission of Fee.**
	Decision of 293rd meeting: Deferred for submission of fee (Rs. 20,000/-) for revising the formulation from doxycycline monohydrate to Doxycycline as hyclate as per the composition of the reference product.	
	Evaluation by PEC: The firm has submitted Rs. 20,000/- vide challan no. 0768949 dated 11/03/2020 for revision of formulation as per the reference product. The following is the correct label claim of the applied product. Each capsule contains: Doxycycline as hyclate…….100mg **Decision: Approved.**	
1981.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Midaz 7.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38054 dated 19-11-2018 Rs.20,000/-
	Composition	Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg
	Pharmacological Group	Sedative/Hypnotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's price Rs. 200/-, 20's price Rs. 250/-
	Approval Status of Product in Reference Regulatory Authorities	Dormicum (7.5mg & 15mg) film coated Tablets by M/s CHEPLAPHARM Arzneimittel GmbH, Netherlands Approved.
	Me-too Status	Dorminic Tablets 7.5mg tablet by M/s Dosaco Laboratories, Reg No. 24295
	GMP Status	The firm was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). Alternate brand name: Mezolam Saf-mif • The firm has revised the formulation of applied product from **Midazolam as Hydrochloride** to **Midazolam as Maleate** and submitted fee Rs. 5000/- vide challan number 0828860 dated 12/12/2019.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
	Evaluation by PEC: The firm has submitted remaining fee of Rs. 15,000/- vide challan number 0828873 dated 17/02/2020 for revision of formulation as per the reference product. Following is the correct label claim of the product. Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg **Decision: Approved with innovator's specifications.**	
1982.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	TARADOL tablet 37.5mg/325mg
	Diary No. Date of R& I & fee	Dy.No. 35264 dated 24/10/2018 PKR 20,000/-
	Composition	Each Film Coated tablet contains: Tramadol hydrochloride…….37.5mg Paracetamol…….325mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	2×10's, Price as recommended by PRC
	Approval Status of Product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP Status	Last inspection report dated 26/10/2018, the firm is not found working as required under the law rule.
	Remarks of the Evaluator.	
	Decision of 293rd meeting**:** Registration Board referred the case to QA & LT Division to conduct GMP inspection of firm on priority.	
	Evaluation by PEC: The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved.**	
1983.	**Name and address of manufacturer / Applicant**	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Diary No. Date of R& I & fee	Dy.No 35106 dated 23-10-2018 Rs.20,000/- Dated 22-10-2018
	Brand Name +Dosage Form + Strength	Velanef 800mg Tablets
	Composition	Each Film Coated Tablet Contains: Sevelamer HCL…800mg
	Pharmacological Group	Phosphate Binder
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renagel 800mg Tablet by M/s Genzyme Corporation, (USFDA approved)
	Me-too status	Renavel 800mg Tablet by M/s AllianzeMed Pharmaceuticals (Reg No:075510)
	GMP status	26-10-2018. The firm is not found working as required under the law/rule
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for updated GMP status of the firm from QA&LT Division. **Evaluation by PEC:** The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved with innovator's specifications.**	
1984.	Duplication	
1985.	**Name and address of manufacturer / Applicant**	AJM Pharma, Plot No. 44, sector No. 27 korangi Inustrial Area Karachi
	Brand Name +Dosage Form + Strength	Asclop tablet 75mg/75mg
	Diary No. Date of R& I & fee	Dy. No. 1315 dated 03/05/2017 Re. 20,000/-
	Composition	Each film coated tablet contains: Clopidogrel as bisulfate…. 75mg Acetyl salicylic acid……75mg
	Pharmacological Group	ADP induced platelet aggregation inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 220/- per pack of 10's
	Approval Status of Product in Reference Regulatory Authorities	CoPlavix Tablet Clopidogrel (as hydrogen sulfate) and aspirin by M/s sanofi-aventis, (TGA Approved)
	Me-too Status	Clodril Plus Tablet M/s Macter International, Reg. No. 55982
	GMP Status	Same as for the previous case
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP).

		Alternate brand names: Asplat Clopiclot
	Decision of 293rd meeting: Deferred for clarification of the dosage of the Innovator product, whether bilayer tablet or otherwise. Evaluation by PEC: The firm has submitted the applied product is not bilayered while it is immediate release film coated tablet. The statement has not been verified from EMA assessment report. The product approved in EMA is bilayered. **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee along with the proof of availability of bilayer tabletting machine.**	
1986.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.2
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….20mg
	Composition	Dy. No. 7989 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ezetimibe and Atrovastatin calcium (USFDA)
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section. Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
1987.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.4
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….40mg
	Composition	Dy. No. 7990 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference	Ezetimibe and Atrovastatin calcium (USFDA)

	Regulatory Authorities	
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section. Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
1988.	Name and address of manufacturer/Applicant	M/s Pharmix Laboratories (Pvt.) Ltd., 21-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Prozol Capsule 30mg
	Composition	Each capsule contains: Enteric coated pellets eq. to Lansoprazole….30mg (Source of Pellet M/s Murli Krishna Pharma Pvt. Ltd. D-98, Ranjangaon, Taluka-Shirur, Pune 412209 Maharashtra state, India)
	Diary No. Date of R& I & fee	Dy. No. 32736 dated 02-10-2018, Rs. 15,000/- dated 15-10-2009, and Rs. 85000/- dated 22-09-2016
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs.425/Pack of 14's
	Reference Regulatory Authorities status	Lansoprazole 30 mg gastro-resistant capsules (UK)
	Me-too status	Arcozol Capsules 30mg of M/s Pakistan Pharmaceutical Products (Pvt) Ltd, Karachi
	GMP status	GMP inspection by inspectors dated 31-05-2018 & 01-06-2018 shows the acceptable level of compliance of GMP.
	Remarks of the Evaluator	Provided stability studies of Lansoprazole pellets 8.5%w/w at 30±2^{0}C, 65%±5% RH of 12 months and at 25±2^{0}C, 60%±5% RH of 48 months
	Decision of 293rd meeting: Deferred for submission of stability data of pellets through shelf life as per Zone IVA. Submission by the firm**:** The firm has submitted long term stability study data of 03 batches for 36 months period according to the conditions of zone IV-A. However, accelerated stability data is not submitted. **Decision: Deferred for submission of Accelerated Stability data of 03 batches of pellets.**	
1989.	Name and address of manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories, Plot # 9A, St#N-5, National Industrial Zone, (RCCI) Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Soulpride 50mg Tablet
	Diary No. Date of R& I & fee	Diary No, Date of R & I & fee Dy. No. 22438 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Composition	Each tablet contains: Levosulpride……..50mg

	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Inovator's specification
	Pack Size & Demanded Price	20's & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	
	Me-too Status	Sulprex Tablets 50mg of M/s Global Pharmaceuticals GMP Status DML by way of formulation No. 000871 dated 13-09-2017.
	GMP Status	Could not be confirmed
	Remarks of the Evaluator.	
	Decision of 292nd meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by AIFA Italy. LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved. Each tablet contains: Levosulpride……..50mg GMP status of the firm could not be confirmed. **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
1990.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, Faisalabad Road Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 60mg Injection
	Composition	Each vial contains: Artesunate ……60mg
	Diary No. Date of R& I & fee	Dy. No 28674 Dated 27-08-2018, Rs. 50,000/- dated 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Gen-M 60mg Injection of M/s Genix Pharma (Pvt) Ltd.
	GMP status	M/s Nabiqasim Industries Pvt. Ltd: DML by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP M/s Surge Laboratories Pvt. Ltd: cGMP inspection dated 05-05-2019 shows good level of cGMP compliance of the firm.
	Remarks of the Evaluator	
	Decision of 292nd meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Now the firm has submitted the evidence of WHO recommended formulation which is access dated 06th December 2019 http://archives.who.int/eml/expcom/expcom15/applications/formulations/artesunate.pdf Decision of 293rd meeting: Deferred for evidence of approval of requisite manufacturing facility from licensing division. Submission by the firm: The applicant has submitted that M/s Surge Laboratories was granted Additional section of Dry Powder Injectable (General) vide letter No. F.1-18/95-Lic(Vol-III) dated 7th July, 2020. The copy of letter is attached with the submission. **Decision: Approved with innovator's specifications.**	

Case No. 2. Registration Applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases (Local manufacturing) Veterinary

1991.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	MAXIFLOR 30% Oral Liquid
	Diary No. Date of R& I & fee	Dy.No. 35265 dated 24/10/2018 PKR 20,000/-
	Composition	Each 100ml contains: Florfenicol……30% (w/v)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack Size & Demanded Price	Plastic bottle of 100ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 18/08/2017 concludes the overall GMP compliance level as good.
	Remarks of the Evaluator.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

b. Deferred cases (local manufacturing) Veterinary

1992.	Name and address of Applicant/ Manufacturer	M/s Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur
	DML	DML by way of formulation dated 25-10-2015.
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 16299 Dated 03-05-2018
	Fee including differential fee	Rs. 20,000/- Dated 02-05-2018
	Brand Name +Dosage Form + Strength	MOXY CS POWDER
	Composition	Each 1000gram contains: Amoxicillin Trihydrate……150gm Colistin sulphate……25gm
	Finished Product Specification	Firm claim innovator's specification
	Pharmacological Group	Antibiotic
	Demanded Price	Decontrolled
	Pack size	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg
	Me-too status	Moxicoli water soluble powder of m/s zumars pharma (pvt) ltd. Karachi.
	GMP status	GMP inspection dated 03-10-2018 **Conclusion:** During the inspection, some suggestions were given for improvement and certain shortcomings were also identified. The Firm's management looked committed in rectifying the shortcomings and assured to do so in the shortest possible time. Therefore, keeping in view the environmental, manufacturing and quality control facilities provided, discussions made with the technical personnel, the documentations presented and reviewed, the raw materials

		consumed in manufacturing of the registered products and commitment of the firm's management in rectifying the shortcomings, the firm M/s Farm Aid Group Haripur is considered to be maintaining satisfactory level of the cGMP and found to be fulfilling GMP requirements
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for evidence of approval of requisite maujfacturing facility (penicillin) from licensing division. **Submission by the firm:** The firm has submitted approval letter No.F.3-9/91-Lic(Vol-I) dated 21st June, 2017 for Dry Powder Section (Vet) section. **Decision: Deferred for confirmation of required manufacturing facility "Dry Powder penicillin (Veterinary)" section.**	

Case No. 3: **Registration Applications of Newly Granted DML or New Section (Veterinary)**

a. New Section:

Vet New Section

M/s Medi-Excel Pharmaceutical, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad was granted additional sections vide letter no. F.1-2/2001-Lic (Vol-I) dated 29/09/2019. The firm has applied for following products against relevant sections as under.

GENERAL INJECTABLE SECTION (VET) NEW One product/molecule was approved in 294th meeting of Registration Board in General Injectable Section (Vet). Further 9 molecules and 29 products are remaining.		
NO OF MOLECULES		**NO PRODUCTS**
9		**31**
1993.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20823 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
1994.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20824 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)

	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
1995.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20825 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
1996.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20826 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
1997.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20827 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	

1998.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20828 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
1999.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20829 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2000.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20830 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2001.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains:

		Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20831 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2002.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains: Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20832 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2003.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"
	Diary No. Date of R& I & fee	Dy. No 20833 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2004.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"
	Diary No. Date of R& I & fee	Dy. No 20834 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2005.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20835 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2006.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20836 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2007.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20837 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No.

		000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2008.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20838 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2009.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20839 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2010.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20840 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2011.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700,

		Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20841 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection 100ml vial of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2012.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20842 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2013.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20843 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.

	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2014.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20844 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2015.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20845 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2016.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20846 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	

	Decision: Approved.	
2017.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20847 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Forte Injection **50ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 102087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2018.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20848 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec forte injection 50ml vial by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2019.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20849 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled

	Me-too status (with strength and dosage form)	Actimec forte injection **50ml vial** by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2020.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone……. 50 mg"
	Diary No. Date of R& I & fee	Dy. No 20853 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2021.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone…….50 mg"
	Diary No. Date of R& I & fee	Dy. No 20854 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The applied filled volume of 50ml is not approved while other filled volumes that 10ml, 20ml, 40ml and 100ml are approved.
	Decision: The Board approved the case with innovator's specifications with a filled volume of 50mL as already approved filled volumes range from 10mL to 100mL.	
2022.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	" Each ml contains: Closantel……...50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20857 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification

	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specfiications.	
2023.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	"Each ml contains: Closantel……...50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20858 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
BOLUS SECTION (VET) NEW		
NO OF MOLECULES		**NO PRODUCTS**
10		13
2024.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 152 Bolus
	Composition	"Each bolus contains: Albendazole……..152 mg"
	Diary No. Date of R& I & fee	Dy. No 20810 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-S Bolus 152mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043139)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2025.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 600 Bolus
	Composition	" Each bolus contains Albendazole……600 mg"
	Diary No. Date of R& I & fee	Dy. No 20811 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled

	Me-too status (with strength and dosage form)	Albensel-C Bolus 600mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043138)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2026.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 2500 Bolus
	Composition	" Each bolus contains Albendazole……2500 mg"
	Diary No. Date of R& I & fee	Dy. No 20812 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-2500 Bolus 2500mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043137)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2027.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flumexcel 350 Bolus
	Composition	" Each bolus contains Flumequine…….350 mg"
	Diary No. Date of R& I & fee	Dy. No 20813 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Flumequine Bolus 350mg of M/s Zakfas Pharmaceuticals Pvt Ltd, (Reg.# 074754)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2028.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Fenexcel 750 Bolus
	Composition	"Each bolus contains: Fenbandazole…….750 mg"
	Diary No. Date of R& I & fee	Dy. No 20814 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Fenbal-Bolus 750mg of M/s Wimits Pharmaceuticals Pvt Ltd, (Reg.# 078319)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2029.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nicloexcel 1250 Bolus
	Composition	"Each bolus contains: Niclosamide……1250 Mg"
	Diary No. Date of R& I & fee	Dy. No 20815 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Niclover Bolus 1250mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046572)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2030.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Santexcel 500 Bolus
	Composition	"Each Bolus contains: Closantel…….500 Mg"
	Diary No. Date of R& I & fee	Dy. No 20816 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Flukinil Bolus 500mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046571)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2031.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Trileva 99 Bolus
	Composition	"Each Bolus contains: Triclabendazole……900 mg Levamisole HCl……90 mg"
	Diary No. Date of R& I & fee	Dy. No 20817 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribazole Plus Bolus 900mg/90mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 074039)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2032.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700,

		Pakistan"
	Brand Name +Dosage Form + Strength	Trissen 1000 Bolus
	Composition	"Each Bolus contains: Trimethoprim……200 mg Sulphadiazine ……..1000 mg"
	Diary No. Date of R& I & fee	Dy. No 20818 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribactral Bolus 200mg/1000mg of M/s Selmore Pharmaceuticals, (Reg.# 029617)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2033.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Suldimexcel 2.5 Bolus
	Composition	"Each Bolus contains: Sulphadimidine Sodium…….2.5 Gm"
	Diary No. Date of R& I & fee	Dy. No 20819 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Sulfapri Bolus 2.5gm of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 063683)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2034.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermexcel Bolus
	Composition	"Each Bolus contains: Levamisole HCl……1125 mg Oxyclozanide……2250 mg"
	Diary No. Date of R& I & fee	Dy. No 20820 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Zanisol Bolus1125mg/2250mg of M/s Prix Pharmaceuticals, (Reg.# 044979)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2035.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 400 bolus
	Composition	"Each bolus contains:

		Levamisole HCl……..400 mg"
	Diary No. Date of R& I & fee	Dy. No 20821 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	LEVA 400 BOLUS of M/s Intervac, (Reg.# 072651)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2036.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 1125 Bolus
	Composition	"Each bolus contains: Levamisole HCl……..1125 mg"
	Diary No. Date of R& I & fee	Dy. No 20822 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Levasel Bolus 1125mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 029618)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

Case No. 4: **Registration Applications of Import Cases.**

a. New Cases Human Import

2037.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.
	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No: 8137 Dated : 25/02/2019
	Fee including differential fee	Rs: 50,000 Dated : 25/02/2019
	Brand Name +Dosage Form + Strength	Amomax 3g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…….2g Salbactum sodium equivalent to Salbactum……..1g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 608/- per vial (1's)

	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	N/A
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052203 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.
	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China authorized M/s biocare.
	Decision: Approved as per policy for inspection of manufacturer abroad.	
2038.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.
	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 8136 Dated : 25/02/2019
	Fee including differential fee	Rs : 100,000 Dated : 25/02/2019
	Brand Name +Dosage Form + Strength	Amomax 1.5g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…. 1g Salbactum sodium equivalent to Salbactum….. 0.5g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 407/- per vial (1's)
	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	To be confirmed
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052202 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.

	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2039.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	Drug license by way of whole sale Address: Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2, 2nd floor West Land trade centre plot no. C-5, Block 7/8, KCHSU, Shaheed e Millat road Karachi. Validity: 09/10/2020
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1674 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 40mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)……40mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 27/- per Cap
	International availability	Losec Capsule 40mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.
	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Sole agency agreement is required. Free sale certificate is issued by authority not recognized by WHO.
	Decision: Deferred for submission of sole agency agreement/letter of authorization and confirmation of zone stability under stability studies were conducted..	
2040.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1673 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 20mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)..……20mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 20/- per Cap
	International availability	Losec Capsule 20mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 20mg by M/s Scotmann Pharmaceuticals (Reg#028238)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.
	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Original sole agency agreement is required. Free sale certificate is issued by authority not recongnized by WHO.
	Decision: Deferred for submission Sole Agency Agreement/letter of authorization.	
2041.	Name and address of Applicant	M/s Aster Life Sciences, 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore. Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1215 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 500mg IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..500mg
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 500 mg powder for solution for injection or infusion by M/s Milpharm Limited, MHRA Approved.
	Me-too status	Mopen 500mg Injection by M/s Hilton pharma, Reg. No. 36429.

	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1738 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018 **Free sale:** Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied fromulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to deferred the case for clarification of salt form.	
2042.	Name and address of Applicant	M/s Aster Life Sciences , 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore. Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1216 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 1g IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..1g
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 1g powder for solution for injection or infusion by M/s Hikma, MHRA Approved.
	Me-too status	Mopen 1g Injection by M/s Hilton pharma, Reg. No. 36427.
	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1736 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018

		Free sale: Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied formulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to defer the case for clarification of salt form.	
2043.	Name and address of Applicant	M/s Scilife Pharma (pvt) Limited, Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Laboratorio Eczane Pharma S.A, Laprida 43, Avellaneda, Buenos Aires, Argentina.
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 6951 Dated 19/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 19/02/2019
	Brand Name +Dosage Form + Strength	Xelotab 500mg tablet
	Composition	Each film coated tablet contains: Capecitabine……..500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	24 months
	Pack size & Demanded Price	2083.3/- per 10's, 6250/- per 30's, 12500/- per 60's, 25000/- per 120's
	International availability	Capecitabine 500 mg film-coated tablets by M/s Glenmark Pharmaceuticals Europe Limited, MHRA Approved.
	Me-too status	MERICAP 500MG film coated tablet by M/s Merixil pharma, Reg. No. 81801
	Stability studies	24 months data for real time and 6 months of accelerated data.
	Detail of certificates attached	**Original CoPP** **Certificate No**: 191912 **Certified by:** National Institute of drugs **Date of issuance:** 28/08/2018 **Free sale:** Yes **GMP status:** The facilities and operations conform to WHO-GMP as per CoPP.

	Remarks of the Evaluator.	Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature* *that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16598/2020* *Tariff: 6.12.3* *Amount: ARS 300/-* *Date: 01/20/2020* *Observations*
	Decision: Deferred for review of stability data as per Zone IVA	
2044.	Name and address of Applicant	M/s Zam Zam Pharmaceutical, Suit No. 205,206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi, Pakistan.
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Zam Zam Pharmaceutical , Suit no. 16 Beaumont Road Karachi. Validity: 15/02/2022
	Product License Holder & Manufacturer	**Manufacturer (**Primary and secondary packaging**):** M/s Haupt Pharma amareg GmbH Donaustaufer Strasse 378 DE-93055 Regemsburg, Germany **Analysis and batch release:** M/s Medinova AG Eggbuhlstrasse 28 Zurich, Switzerland **Product License Holder:** Medinova AG Eggbuhlstrasse 28 CH-8050 Zurich Switzerland
	Name of exporting country	Switzerland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 29862 Dated 05/09/2018
	Fee including differential fee	Rs. 50,000/- Dated 05/09/2018 Rs. 5,000/- dated 19/05/2020 for change of product license holder.
	Brand Name +Dosage Form + Strength	Gynoflor Vaginal tablets
	Composition	Each vaginal tablet contains: Lactobacillus acidophilus……100million cfu Estriol……...0.03mg
	Finished Product Specification	Innovators
	Pharmacological Group	Gynecological anti-infective and antiseptic
	Shelf life	36 months
	Pack size & Demanded Price	1 blister of 6 vaginal tablets, Rs. 1875.
	International availability	Approved in Switzerland as per CoPP and the approval status has been verified from official website. Gynoflor vaginal tablet by M/s medinova, Swissmedic
	Me-too status	Could not be confirmed
	Stability studies	36 months data of 3 batches at 5°C±3°C, 60%±5%, Real Time 06 months data of 3 batches at 25°C± 3°C, 60%±5%, Acelerated

	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 20001402 **Certified by**: Swissmedic **Date of issuance:** 20/03/2020 **Free sale:** yes **GMP status:** conforms to WHO-GMP Copy of Distribution agreement is submitted. M/s Medinova AG, Switzerland confirms M/s Zam Zam Pharmaceutical as the exclusive distributor for Pakistan.
	Remarks of the Evaluator.	Lactobaccilus bacilus is a living organism, therefore the content of lactobacillus aciophilus in lyophilisate may vary within the specifications. Manufacturing: 1. Manufacturing of Premix of estriol with cellulose 2. excipients + Acidophilus bacillus lyphilisate Resultant mixtures from both steps ar then finally mixed and compressed.
	Decision: Referred to Committee constituted by DRAP for determining therapeutic group.	
2045.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5744 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SPDROX 500mg capsule
	Composition	Each capsule contains: Hydroxyurea ……500mg
	Finished Product Specification	BP
	Pharmacological Group	antineoplastic (anti-cancer)
	Shelf life	24 Months
	Pack size & Demanded Price	10's & As per SRO
	International availability	Hydroxycarbamide medac 500 mg capsule, hard (Germany)
	Me-too status	HYDREA CPASULES 500MG of M/s BRISTOL MYERS SQUIBB
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2046.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.

	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5745 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SP GEF 250mg tablet
	Composition	Each film coated tablet contains: Gefitinib……250mg
	Finished Product Specification	Firm claim in-house specifications of applied product
	Pharmacological Group	Anticancer
	Shelf life	24 Months
	Pack size & Demanded Price	As per SRO
	International availability	Gefitinib 250 mg film-coated tablets of M/s Cipla (Eu) Ltd., (MHRA approved)
	Me-too status	Could not be confirmed
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	Me too status could not be confirmed.
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2047.	Name and address of Applicant	M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi
	Detail of Drug Sale License	Address: M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi Validity: 24-12-2018 to 23-12-2020 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.
	Name and address of marketing authorization holder	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7465 Dated 04-07-2017
	Fee including differential fee	Rs. 100,000/- Dated 25-08-2014 copy attached.
	Brand Name +Dosage Form + Strength	Cytodrox Hydroxyurea Capsules USP 500mg
	Composition	Each capsule Contains: Hydroxyurea…….500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	36 months: Store below 30ºC.
	Pack size & Demanded Price	10's & As per DPC
	International availability	Hydrea 500 mg Hard Capsule by M/s Bristol myer, MHRA Approved.

	Me-too status	Uro-Z 500mg Capsule by M/s Zjans Pharma, Reg. No. 26792
	Stability studies	Firm has submitted long term (36 months) at 30°C & accelerated (06 months) stability data at 40°C, 75± 5% RH for three batches.
	Detail of certificates attached	Legalized and valid copy of CoPP Certificate No. 789.MFG/WHO-GMP/DFA/2019/164(2) valid till 19/02/2022 is submitted. The product is available I for free sale in country of origin and the manufactuere conforms to WHO-GMP as per CoPP. Copy of agreement is attached.
	Remarks of the Evaluator.	i. Photocopy of fee challan form is attached.
	Decision: Approved with as per Policy for inspection of Manufacturer abroad. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2048.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore
	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020 Address: 73-B Guldashat town, Zarrar Shaheed Road, District Lahore. *the firm has submitted receipt for renewal of license.
	Product License Holder & Manufacturer	M/s S.C. Magistra C&C S.R.L 82A Aurel Vlaicu blvd., Constanta, code 900055, Romania
	Name of exporting country	Romania
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 7571 Dated 28-02-2018
	Fee	Rs. 50,000/- Dated 28-02-2018
	Brand Name +Dosage Form + Strength	Contracept M 18.9mg Pessary
	Composition	Each pessary contains: Benzalkonium chloride……18.9mg
	Finished Product Specification	
	Pharmacological Group	Act code G02BBN2 Local contraceptives
	Shelf life	24 Months
	Pack size & Demanded Price	10's commercial unit & As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed
	Stability studies	Firm has submitted long term (24 months) at 30°C±2°C, 65%RH±5%RH & accelerated (06 months) stability data at 40°C, 75% RH of three batches
	Detail of certificates attached	Legalized and valid copy of CoPP (Certificate#. 5487) issued on 11-10-2017 by Ministry of Health, National Agency for Medicines and Medical Devices declaring the free sale of applied product and GMP compliant status of the manufacturer. Copy of Original Notarized "Product specific Letter of Authorization" from M/s VEM Llac San. Ve Tic. A.S in the name of M/s Bristol Mayer Biotech Pakistan dated 07-06-208 valid for 2 years is submitted
	Remarks of the Evaluator.	i. The product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP. ii. Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. iii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

	Decision: Deferred for the submission of following; • **Calrification is required since the product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech**

b. Deferred Cases (Human) Import

2049.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Manufacturer & Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3702 Dated 28-01-2019
	Fee including differential fee	Rs. 100,000/- Dated 28-01-2019
	Brand Name +Dosage Form + Strength	DASANIB 70mg Tablet
	Composition	Each film coated tablet contains: Dasatinib…….70mg (as Dasatinib monohydrate 72.58mg)
	Finished Product Specification	In-house
	Pharmacological Group	ANTINEOPLASTIC AGENTS, L01XE Protein kinase inhibitors
	Shelf life	24 Months store below 300C
	Pack size	60's
	International availability	SPRYCEL 70mg (USFDA)
	Me-too status	SPRYCEL 70MG TABLETS of M/s BRISTOL-MYERS SQUIBB,
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 20132019 000767 18) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Valid for twelve months Copy of Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 293rd meeting: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. Submission by the firm: The firm has submitted Original and Valid CoPP (certificate No. 191910) issued by National institute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the	

	legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16599/2020* *Tariff: 6.12.3* *Amount: ARS 300 -* *Date: 01/20/2020* *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2050.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36523 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 100mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……100mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temoeirgen 100Mg Capsules of M/s Merixil Pharma
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 291st meeting of Registration Board: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP.	

	"Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic". Decision: **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP. **Submission by the firm:** The firm has submitted Original and Valid CoPP (certificate No. 191914) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16598/2020* *Tariff: 6.12.3* *Amount: ARS 300 .-* *Date: 01/20/2020* *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2051.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Details of Drug sale license	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36524 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 250mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide…….250mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temonat 250mg Capsules of M/s Hakimsons
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires

		Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 291st meeting of Registration Board: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. "Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic" **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP. **Submission by the firm:** The firm has submitted Original and Valid CoPP (certificate No. 191913) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16597/2020* *Tariff: 6.12.3* *Amount: ARS 300 .-* *Date: 01/20/2020* *Observations* **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2052.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore
	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020
	Product License Holder & Manufacturer	M/s VEM Llac San. Ve Tic. A.S. Factory address: Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi. Fatih Bulvari. No: 38 Kapakli/ TEKIRDAG/TURKEY
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18447 Dated : 21/05/2018
	Fee including differential fee	Rs : 50,000 Dated : 21/05/2018 + Rs : 50000 :Dated: 16-10-2019
	Brand Name +Dosage Form + Strength	Candisept 100mg/50ml I.V Solution for Infusion
	Composition	Each 50ml Vial Contains Fluconazole ……100mg
	Finished Product Specification	USP
	Pharmacological Group	Antifungal

	Shelf life	36 Months
	Pack size & Demanded Price	As per SRO
	International availability	Fluconazole 2mg/ml Solution for Infusion (USFDA)
	Me-too status	Lumen 2mg/Ml Injection (50ml) Of M/S Nimrall Farma (Reg # 039823)
	Stability studies	
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/1719 **Certified by:** Turkish Medicines and Medical devices Agency *Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey* Product license and date of issue : 254/16 _05.11.2013 **Valid until :** 03-05-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **GMP certificate and Free sale certificate** Certificate No : 2018/1720 Date of Issue: 03-05-2018 Valid until : 03-05/2020 **GMP certificate:** GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **Sole Contract Agreement** 07-06-2018 Validity: 2 Years

	Deficiencies/Shortcomings	**Reply by Firm**
Remarks of the Evaluator.	Remaining fee of Rs:50000/- as product is already registered in Pakistan.	Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1914215 Dated: 16-10-2019
	Justify use of Type II glass as primary packaging material while in reference agency Type I glass is used as primary packaging material.	According to the European Pharmacopoeia "3.2.1 Glass Containers for Pharmaceuticals Use" Type II glass containers are suitable for most acidic and neutral ,aqueous preparations whether or not for parenteral administration. Our product is near neutral and aqueous solution. Therefore, Type II glass is suitable for this product.

Decision of 293rd meeting:

Deferred for Clarification/Justification on scientific grounds for use of Type II glass container as primary packaging material for applied formulation or otherwise evidence of reference product packed in Type II glass container.

Evaluation by PEC:

The firm has provided the reference of the following product approved by MHRA which has been verified with following details;

Fluconazole 2 mg/ml Solution for Infusion

2. Qualitative and quantitative composition

50 ml/100 ml glass vials:

1 ml solution for infusion contains 2 mg of fluconazole.

6.5 Nature and contents of container

Glass vials:

Clear type I or II glass vial, sealed with chlorobutyl rubber stopper and sealed with a flip-off aluminium cap.

The official website was accessed on 29/06/2020.

https://mhraproductsproduction.blob.core.windows.net/docs/c10d2a9d32a84c9c845161dedc2e587247c0ff58

	Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech	
2053.	Name and address of Applicant	M/s Punjab Medical Services, Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. OPD Gate sir Ganga ram Hospital Mozang Road Lahore License to sell drugs as a Distributor No. 0011000 0002884 Valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul, 34906, Turkey
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE
	Name of exporting country	Greece
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7371 Dated 20-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 50mg/vial
	Composition	Caspofungin Acetate 55.52mg eq. to Caspofungin……50mg
	Finished Product Specification	In-house
	Pharmacological Group	Antimycotics for systemic use
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's
	International availability	CANCIDAS® 50 mg powder for concentrate for solution for infusion (Netherland)
	Me-too status	Not available
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129338) dated 09-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. **Submission by the firm:** The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland.	

	It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2054.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE
	Name of exporting country	Greece
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7370 Dated 20-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 70mg/vial
	Composition	Caspofungin Acetate 77.69mg eq. to Caspofungin……70mg
	Finished Product Specification	In-house
	Pharmacological Group	Antimycotics for systemic use
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's
	International availability	CANCIDAS® 70 mg powder for concentrate for solution for infusion (Netherland)
	Me-too status	Not Available
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129337) dated 08-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. Submission by the firm: The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland.	

	It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2055.	Name and address of Applicant	M/s Mehran International 498 C Hume Road Quaideen Colony Opp: World Map Near 3 Star Hall Karachi-Pakistan
	Manufacturer & Product License Holder	M/s Hebei New Century Pharmaceutical Co. Limited 189 Taihang Street, Hi-tech zone Shijiazhuang, Hebei, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 31413 Dated 18-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-09-2018
	Brand Name +Dosage Form + Strength	Cefquinome Oral Suspension 2.5% 100ml
	Composition	Each ml contains: Cefquinome sulfate…….25mg
	Finished Product Specification	Firm claim innovators specification
	Pharmacological Group	fourth-generation cephalosporin antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1x100ml bottle Oral Suspension
	RRA status	Combactan of MSD USA
	Stability studies	Firm has submitted long term (36 months) at 30+2oC, 65+5%RH & accelerated (06 months) stability data at 40+ 2oC, 75+ 5% RH for three batches.
	Detail of certificates attached	Copy of CoPP is submitted Copy of Provided Sole agency agreement with M/s NINHUA Group Co., Ltd, 21 Jiangxia st. Ningbo, P.R. China which is sole and exclusive exporting subjected products of the manufacturer in Pakistan and manufacturer shall not sell the above-mentioned items to Pakistan marketed by itself or through any other third parties.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of original legalized CoPP from concerned regulatory Authority of exporting country. Submission by the firm: The firm has submitted original legalized CoPP (no.2019121601) issue dby Agricultural office of Shijiazhuang High-tech zone, China on 16/12/2019. The product is available in free sale. The facilitie and operations conform to WHO-GMP. **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	

Miscellaneous deferred cases of Import (Human)

Registration Board in 295th meeting had decided to defer the below mentioned 5 cases and decided that the Secretary Registration Board will confirm from the manufacturer (M/a Shanxi PUDE Pharmaceutical Co., Ltd., MAH Holder) via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.

The reply received from the relevant firm is being reproduced hereby before the Board.

1.

---------- Forwarded message ---------

From: **普德** <pudepharma@yeah.net>

Date: Thu, 3 Sep 2020, 12:46 pm

Subject: Confirmation of Authenticity of Stability Data

To: <abroabdullah@gmail.com>

Dear Abdullah,

Thanks for your email. We confirmed stability data of products for the batches mentioned in below mentioned table is true.

Sr.#	Brand name & Composition	Stability Batch No. & Manufacturing Date
1.	METHOTREXATE for IV injection 50mg/vial Each vial contains: Methotrexate…. 50mg	Batch No: 1845027 Mfg date: June 5, 2017 Batch No: 1845028 Mfg date: June 6, 2017 Batch No: 1845029 Mfg date: June 07, 2017
2.	METHOTREXATE for IV injection 100mg/vial Each vial contains: Methotrexate…. 100mg	Batch No: 19456620 Mfg date: July 09, 2017 Batch No: 19456621 Mfg date: July 10, 2017 Batch No: 19456622 Mfg date: July 11, 2017
3.	METHOTREXATE for IV injection 500mg/vial Each vial contains: Methotrexate…. 500mg	Batch No: 2010100 Mfg date: Aug 15, 2017 Batch No: 2010101 Mfg date: Aug 16, 2017 Batch No: 2010102 Mfg date: Aug 18, 2017
4.	VINORELBINE 10mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg	Batch No: 21000401 Mfg date: Sep 15, 2017 Batch No: 21000402 Mfg date: Sep 16, 2017 Batch No: 21000403 Mfg Date: Sep 17, 2017
5.	VINORELBINE 50mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg	Batch No: 21000404 Mfg date: Sep 18, 2017. Batch No: 21000405 Mfg date: Sep 19, 2017. Batch No: 21000406 Mfg Date: Sep 19, 2017.

Best regards
Shanxi PUDE Pharmaceutical Co., Ltd
Submitted for consideration of the Board.

2056.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3555 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 50mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)

	Composition	Each vial contains: Methotrexate…. 50mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. d. Original, legalized and valid CoPP Evaluation by PEC: a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (1845027 Mfg date:June5, 1845028 Mfg date: June 6, 2017, 1845029 Mfg date:June 07 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product approved in USFDA with same strength and dosage form that is 50mg Powder For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 50mg/2ml solution for injection is approved in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2057.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan

	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3556 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 100mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 100mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (19456620 Mfg date:July 09, 19456621 Mfg date: July 10, 2017, 19456622 Mfg date: July 11, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product approved in USFDA with same strength and dosage form that is 100mg For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 100mg/4ml solution for injection is available in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available.	

	d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2058.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3558 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 500mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 500mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150011) issued by Shanxi Food and Drug Administration valid till 03/11/***2017*** *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC:	

	a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (2010100 Mfg date: Aug 15, 2010101 Mfg date: Aug16, 2017, 2010102 Mfg date: Aug 18, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product (500mg for injection) with same strength and dosage form is not available in reference authorities while 500mg/20ml solution for injection is discontinued for reasons other than safety and efficacy. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2059.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 395 Dated 16-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 15-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 10mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 10mg/ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 10mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially	

	submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. d. The salt form of the drug as it is different from the approved product in reference countries. e. Finished product specifications. Evaluation by PEC: a. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. b. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection. c. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted. d. Firm submitted CFDA standard specification. e. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000401 Mfg date: Sep 15, 2017, 21000402 Mfg date: Sep 16, 2017, 21000403 Mfg Date: Sep 17, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. f. Salt form	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2060.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3560 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 50mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*

	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 50mg/5ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 50mg/vial.

Decision of 274th meeting of Registration Board: Registration Board deferred the cases for:

a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true
b. Detail of diluent to be used for reconstitution.
c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
d. The salt form of the drug as it is different from the approved product in reference countries.
e. Finished product specifications.
f. Sole agency agreement

Evaluation by PEC:

a. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL.
b. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection.
c. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted.
d. Firm submitted CFDA standard specification.
e. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000404 Mfg date: Sep 18, 2017, 21000405 Mfg date: Sep 19, 2017, 21000406 Mfg Date: Sep 19, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data.
f. Salt form

Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.

Decision: Approved with innovators specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.

Registration Board in 295th meeting had decided to defer the below mentioned 02 cases and decided Secretary Registration Board will confirm from the manufacturer via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.

The reply received from the relevant firm is being reproduced hereby before the Board.

Dear ABDULLAH

Sorry for my late reply.

we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg: Each ampoule (2mL) contains: Irinotecan hydrochloride trihydrate……40mg	19277800	Oct 20, 2017
		19277801	Oct 21, 2017
		19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg:	19277803	Oct 23, 2017
		19277804	Oct 24, 2017

	Each ampoule (5mL) contains: Irinotecan hydrochloride trihydrate……100mg	19277805	Oct 25, 2017

Please see attachment for STATEMENT.
Best regards!
Anna
Cisen Pharmaceutical Co., Ltd.
Add: Tongji Sci-tech Industrial Park, High-tech Industrial Development Zone, Jining, Shandong, P.R. China. 272073
Tel: +86 537 2980071 +86-18678761518
---------- Original ----------
From: "wangsh"<wangsh@cisengroup.com>;
Date: Sat, Aug 29, 2020 04:52 PM
To: "Abdullah Abro"<abroabdullah@gmail.com>;
Cc: "selina"<selina@nbpharm.com>; "shirlyran"<shirlyran@nbpharm.com>; "Obaidullah Malik"<obaiddr@yahoo.com>;
Subject: Re:Confirmation of Authenticity of Stability Data

Aug.31, 2020

STATEMENT

To whom it may concern,

Hereby, we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg: Each ampoule (2mL) contains: Irinotecan hydrochloride trihydrate……40mg	19277800	Oct 20, 2017
		19277801	Oct 21, 2017
		19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg: Each ampoule (5mL) contains: Irinotecan hydrochloride trihydrate……100mg	19277803	Oct 23, 2017
		19277804	Oct 24, 2017
		19277805	Oct 25, 2017

Sincerely yours,
Quality Management Department
For and on behalf of
Cisen Pharmaceutical Co. Ltd.

2061.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.

		Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 40mg
	Composition	Each ampoule (2ml) contains: Irinotecan…… 40mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066186)
	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/62246) issued by Jining Food and Drug Administration valid till 14/12/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted (dated 15th August 2017, and after that on dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (2ml) contains: Irinotecan…… 40mg CoPP valid till 14-12-2017 Copy of valid DSL Composition different from reference?	
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg)	

	Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (19277800 Mfg date: Oct 20, 2017, 19277801 Mfg date: Oct 21, 2017, 19277802 Mfg Date: Oct 22, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 14/12/2017.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2062.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 100mg
	Composition	Each ampoule (5ml) contains: Irinotecan…… 100mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066187)
	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/47074) issued by Jining Food and Drug Administration valid till 16/09/2017 **declaring the free sale of applied product and GMP compliant status of the manufacturer.**
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted	

	after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted data dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (5ml) contains: Irinotecan…… 100mg CoPP valid till 16-09-2017
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (1977803 Mfg date: Oct 23, 2017, 19277804 Mfg date: Oct 24, 2017, 19277805 Mfg Date: Oct 25, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 16/09/2017.
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**

c. New cases (Import) Veterinary

2063.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Drug Sale License	M/s Geevet International Naz Medicine Market Namak Mandi Peshawar Whole sale / distributor Valid till 01/01/2022.
	Name and address of manufacturer	**Manufacturer and MAH:** M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27773 Dated 13-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 13-08-2018
	Brand Name +Dosage Form + Strength	Lincocid Gold soluble powder
	Composition	Each gram contains: Spectinomycin base…..444mg Lincomycin base……..222mg
	Finished Product Specification	Chinese Pharmacopoeia
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1kg, 500gm, 250gm
	Me-too status	LINCO-S 100 W/S POWDER by M/s Attabak, Reg. No. 062169

	Stability studies	Firm has submitted long term (24 months) at 30°C 65% RH & accelerated (06 months) stability data at 40°C, 75% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (Certificate#. 05019)** Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023 Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2064.	Name and address of Applicant	M/s Qualivet Pharma, No.5/15, Ground Floor, Survey No.79, Golden town, Karachi.
	Detail of Drug Sale License	**Address:** M/s Qualivet Pharma, H.No. 5/15 Groud floor, survey no.79 golden town Karachi. **Validity:** 26-11-2019 **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of WHOLE SALE by manufacturer, importer or intender.
	Name and address of manufacturer	M/s Laboratory Karizoo SA, , Mas Pujades, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain.
	Name and address of marketing authorization holder	M/s Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 32632 Dated 01-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 01-10-2018
	Brand Name +Dosage Form + Strength	LEVOFLOK 100mb/ml Oral Solution
	Composition	Each ml contains: Enrofloxacin……..100mg
	Finished Product Specification	Mfg specs
	Pharmacological Group	Abtibacterial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	250ml, 1Litre, 5Litre
	International availability	Available in Spain for free sale as per CoPP
	Me-too status	ROXIN 10% ORAL SOLUTION by M/s M&H PHARMACEUTICALS LAHORE (Imported) Reg. No. 015495
	Detail of certificates attached	**Original Legalized CoPP:** **Certificate No:** Nil **Certifying Authority:** Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Issue Date:** 10/05/2018 **Free sale in exporting country:** Yes **Applicant of certificate:** Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain. **GMP:** • **Original legalized GMP Certificate** **Certificate no.** ES/135HV/19 **Manufacturer Address:** M/s Laboratory Karizoo SA, Mas Pujades, 5-10, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain.

		Issued by: Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Status:** valid till 23/04/2022
	Remarks of the Evaluator:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Moreover the applicant will provide the valid copy of Drug sale License.	
2065.	**Name and address of Applicant**	M/s Hassan Brothers House No. 318 St. # 6 Fatehabad Sharqi, Satiana Road Faisalabad
	Detail of Drug Sale License	M/s Hassan Brothers Ground floor P. 318 St. # 6 Mohallah Fateh abad Sharqi, Satiana Road Faisalabad License to sell drugs as a distributor No: 0011000 0001570 valid upto *29-March-2020. *The firm has submitted the receipt for renewal of DSL dated 24/06/2020.
	Product License Holder & Manufacturer	Head office: M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea Factory: M/s Samyang Anipharm co. Ltd. 35, Songseon-ro 265 beon-gil, Pocheon-si, Gyconggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 42885 Dated 17-12-2018
	Fee including differential fee	Rs. 100,000/- Dated 17-12-2018
	Brand Name +Dosage Form + Strength	FLOCOL-200 SOLUTION
	Composition	Each ml contains: Florfenicol….200mg
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Pack size & Demanded Price	500ml, 1L, 2.5L & 5L
	International availability	Korea
	Me-too status	TEMPRO-20% LIQUID by M/s Ras Pharma, Reg. No. 96838
	Stability studies	Real Time data for 24 months Accelerated data for 6 months as per Zone-IVA submitted.
	Detail of certificates attached	• Original Legalized FSC (Certificate#. M1813617) issued on 02-10-2018 by Animal and Plant Quarantine Agency Korea declaring the free sale of applied product in country of origin Korea. • Original Legalized GMP issued by Animal and Plant Quarantine Agency Korea dated 02-10-2018. • Original sole agency agreement is submitted. M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea appointed M/s Hasssan Brothers Faisalabad as Distributor for Pakistan for the applied product.
	Remarks of the Evaluator.	
	Decision: Approved as per policy for inspection of manufacturer abroad.	
2066.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 25112 Dated 19-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-07-2018
	Brand Name +Dosage Form + Strength	Bravecto 1000mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	The submitted stability data contains the results of only initial time point. Submit 06 months accelerated stability and 24 months real time stability study data according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2067.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21640 Dated 20-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 20-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 112.5mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……112.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	

	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2068.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21052 Dated 12-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 08-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 250mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.**	

	• **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2069.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 17307 Dated 10-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-05-2018
	Brand Name +Dosage Form + Strength	Bravecto 500mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product. Me-too status of the product
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2070.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9004 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019

	Brand Name +Dosage Form + Strength	Reefmox oral powder 50%
	Composition	Each gram contains: Amoxicillin trihydrate…… 500mg
	Finished Product Specification	
	Pharmacological Group	Antiobiotic
	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00079. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decsion: Deferred for the following: • **Provide product specific sole agency agreement.** • **Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2071.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9002 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Neoreef 500 oral powder
	Composition	Each gram contains: Neomycin sulphate…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic

	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00078. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license**.	
2072.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9003 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Reedox 500 oral powder
	Composition	Each gram contains: Doxycycline HCl…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00077. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement.

		Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2073.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain **Exporter:** MPA Vetrinary Medicines and Additives S.L. C/Mogoda, 16-18 Pol. Ind. Can Salvatella. Barbera del Valles. Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 4657 Dated 01/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Linesvall 150mg/ml solution for injection
	Composition	Each ml contains: Lincomycin as hydrochloride…….50mg Spectinomycin as sulphate tetrahydrate…….100mg
	Finished Product Specification	In House
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml vial, Price decontrolled
	Me-too status	BIO-LINCO-S INJECTION. 200/50mg per ml by M/s International chempharma Reg. No. 39967
	Stability studies	36 months data according to the conditions of zone IV-A of 3 batches is submitted. Accelerated data is not submitted.
	Detail of certificates attached	Legalized Free sale certificate issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.

	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2074.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 4658 Dated 01/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Tilovall 200mg/ml solution for injection
	Composition	Each ml contains: Tylosin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Pack size & Demanded Price	Price decontrolled, 100ml vial
	Me-too status	BILOSIN 200MG/ML SOLUTION FOR INJECTION by M/s Binsadiq International, Reg. no. 84841
	Stability studies	24 months real time, 06 months accelerated stability
	Detail of certificates attached	Legalized Free sale certificate for Tilovall 200mg/ml issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2075.	Name and address of Applicant	M/s ZS Biotech Animal Health Company. 50-C Madina Block Awan Town Multan Road, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Farmabse Saude Animal Ltda Av. Emilio Marconato, nº 1000-Galpao A-Jaguariuna (SP) Brazil.
	Name of exporting country	brazil
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 2972 Dated 23/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 23/01/2019

	Brand Name +Dosage Form + Strength	Farmadox 50 oral powder
	Composition	Each 100 gram contains: Doxycycline hyclate……. 50gm
	Finished Product Specification	
	Pharmacological Group	tetracycline
	Shelf life	2 years
	Pack size & Demanded Price	200gm & 25kg, price decontrolled
	Me-too status	
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Original and legalized free sale certificate is submitted while legalized free sale with English translation is required. As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify. Submit 06 months accelerated stability studies of 03 batches. Valid copy of Drug Sale License is required. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following; • **Original and legalized free sale certificate is submitted while legalized free sale with English translation is required.** • **As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify.** • **Submit 06 months accelerated stability studies of 03 batches.** • **Valid copy of Drug Sale License is required.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2076.	Name and address of Applicant	M/s Orient Animal Health (pvt) ltd. Commercial #6, Block-A, 1st floor, Kazimabad, Near Masjid e Hira, Model Colony, Karachi.
	Detail of Drug Sale License	Drug License by way of wholesale Address: Orient Animal Health (PVT) LTD. Comm-6 Block-A Ist floor Kazimabad, Model Colony Karachi. Godwon: Ground floor C-14 Block-A Kazimabad Model Colony Karachi. Validity: 22/10/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Univet Ltd., Tullyvin, Cootehill, County Cavan, H16 T183 , Ireland.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1689 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Solu-Flox 100mg/ml solution for use in drinking water
	Composition	Each ml contains: Enrofloxacin…… 100mg
	Finished Product Specification	In House
	Pharmacological Group	Anti bacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml, 1 litre, 5 litre, price decontrolled

	Me-too status	ENROFLOX SOLUTION (10gm/100ml) by M/s Biorex, Reg. No. 031528
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate. Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.
	Decision: Deferred for the following: • **Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate.** • **Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.**	
2077.	Name and address of Applicant	M/s HPI Pharma, Bao wala Opposite truck stand gate no. 2 Rasheed Abad, Jhang Road Faisalabad.
	Detail of Drug Sale License	Drug License by way of wholesale Address: HPI Pharma, Ground floor P-171 Medol Town-B, District Faisalabad. Karachi. Validity: 08/08/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Industrial Veterinaria, S.A Esmeralda 19, 08950 Espulgues de Llobregat Barcelona, Spain.
	Name of exporting country	spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5170-B Dated 06/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 06/02/2019
	Brand Name +Dosage Form + Strength	Pluscolan concentrate for oral solution
	Composition	Each ml contaions: Colistin sulfate……..5,000,000 IU
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Pack size & Demanded Price	100ml, 1litre, 5litre, price decontrolled
	Me-too status	
	Stability studies	24 moths real time and 06 months accelerated of 3 batches as per ZONE IV-A.
	Detail of certificates attached	Original legalized free sale certificate issued on 06/07/2018, the product is freely sold in exporting country and the manufacturer conforms to WHO-GMP as per the certificate.
	Remarks of the Evaluator.	Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only.

		Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

d. Case no. 4: Deferred cases (Import) Veterinary

2078.	**Name and address of Applicant**	**M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore**
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Vetmulin 450mg/g Water soluble granules
	Diary No. Date of R& I & fee	Dy No. 336 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Tiamulin hydrogen fumarate ……450 mg
	Target Specie	Chicken, Turkey
	Pharmacological Group	ATC Vet Code: QJ01XQ01 Antibacterials for systemic use, Pleuromutilins
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years (supported by accelerated and real time stability data)
	Pack size & Demanded Price	1 kg sachet
	Approval status of product in Reference Regulatory Authorities.	Vetmulin (Denmark Approved) HPRA Approved
	Me-too status	006846 TIAMUTIN 45% HILTON KARACHI
	CoPP/GMP status	**Original, legalized certificate of origin and free sale** issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale **Copy of GMP certificate** (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food **Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria**
	Remarks of the Evaluator.	**Withdrawal Period:** Chickens

		Meat and offal: 3 days Eggs: Zero days Turkeys Meat and offal: 5 days ● The address of manufacturing site on GMP certificate is "39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria" which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag.
	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate. Decision of 285th meeting of Registration Board: "Deferred for above clarifications" Now the firm has submitted the following documents: a. Vetmulin 450mg/g It is a 1kg sachet. b. Original Legalized CoPP (Certificate#. BG 6/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria) c. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2079.	**Name and address of Applicant**	M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore

	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) **48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufactures)**
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Tilmovet 250mg/ml Concentrate for oral solution
	Diary No. Date of R& I & fee	Dy No. 337 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each ml contains Tilmicosin ……250 mg
	Target Specie	Chicken (Broiler, pullets), Turkey and Calves
	Pharmacological Group	Antimicrobials for systemic use, macrolides ATC vet code: QJ01FA91
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Pack size & Demanded Price	960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper-evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET. 60 mL PET vials with closure of PET/PE
	Approval status of product in Reference Regulatory Authorities.	HPRA Approved
	Me-too status	044909 HICOS 250 ORAL SOLUTION HILTON PHARMA (PVT) LTD., KARACHI.
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale Copy of GMP certificate (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate
	Remarks of the Evaluator.	Withdrawal Period: Calves: 42 days. Chickens: 12 days Turkeys: 19 days Eggs: Not authorized for use in birds producing eggs for human consumption. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD.
	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form

		5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder **mentioned on Form 5A. Clarification is required.**
	Fresh Evaluation: a. **Clarification for type of container whether you have applied for sachet or bag.** 960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET.60 mL PET vials with closure of PET/PE. b. **The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence.** **(QC and Batch Release+Headquarter)** Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria **(Manufactures)** 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. **The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.** Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate. **Decision of 285th meeting of Registration Board:** "Deferred for above clarifications" Now the firm has submitted the following documents: a. Tilmovet 250mg/ml concentrate for oral solution is packed in 3 container types and sizes: High density polyethylene (HDPE) bottles of 960ml with vertically see-through bar and a graduated scale provided with white tamper evident closure made of PP with white foamed sealing disk. High-density polyethylene (HDPE) bottles of 240ml with a closure made of polyethylene terephthalate (PET). Polyethylene terephthalate (PET) vials of 60ml with a closure made of polyethylene terephthalate/polyethylene (PET/PE). **(**Provided stability data is of only 240ml bottle) b. Original Legalized CoPP (Certificate#. BG 7/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria) c. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2080.	**Name address of Applicant**	M/s Saadat International, 117 Habitat Flat Shadman II Jail Road Lahore
	Drug Sale License	**Address**: 117 Habitat Flat Shadman II Jail Road Lahore Lahore **Validity:** 12-06-2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria

		(QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	HydroDoxx 500mg/g Powder for use in drinking water
	Diary No. Date of R& I & fee	Dy No. 335 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Doxycycline (as hyclate) ……500 mg
	Pharmacological Group	ATC Vet Code: QJ01AA02.: Antibacterial for systemic use; tetracyclines Tetracycline
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Target Specie	Chicken Broiler
	Shelf life	3 years (supported by accelerated and real time stability data) Shelf-life of the veterinary medicinal product as packaged for sale: 36 months(HPRA)
	Pack size & Demanded Price	1kg sachet
	Approval status of product in Reference Regulatory Authorities.	Ireland Approved HPRA
	Me-too status	023470 Doxyveto- 50 S Soluble Powder Vmd Pakistan Rawalpindi
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale. Copy of GMP certificate (No. 64/2017/GMP) issued on 01-13-2017 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria
	Remarks of the Evaluator.	Withdrawal Period: Meat and offal: Chicken : 6 days Not authorized for use in laying birds producing eggs for human consumption Do not use within 4 weeks of onset of the laying period. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag

	(M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale Certificate.	
	Decision of 285th meeting of RB: Deferred for above clarifications Now the firm has submitted the following documents: a. It is a 1kg sachet b. **Original Legalized CoPP (Certificate#. BG 5/2019)** issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company**, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria**. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: **39, Petar Rakov Street,** 4550 Peshtera, Bulgaria while address of manufacturing site is **48 vasil Petleshkov street**, Peshtera 4550, Bulgaria) c. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2081.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26825 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	COLMYC 20% Oral solution for administration in drinking water
	Composition	Each ml contains: Enrofloxacin…….200mg

	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	3 years store below 30^0C
	Demanded Price	Decontrolled
	Pack size	500ml, 1L,5L
	Me-too status	EL-FLOXACIN LIQUID of M/s ELKO ORGANISATION,
	Stability studies	Firm has submitted long term (36 months) at 30°C 75±5%RH & accelerated (06 months) stability data at 40°C, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 14th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	Applied product is **Suspension as per USP monograph but applied product is solution dosage form**.
	Decision of 292nd meeting of Registration Board: Deferred for following: Applied product is suspension as per USP monograph, but applicant apply solution dosage form. M/s Poul Med submitted that the European Pharmacopoeia monograph number 2229 for Enrofloxacin (Enrofloxacin for veterinary use) is the only monograph available for Enrofloxacin in the European Pharmacopoeia. It describes the tests and specifications that the raw material (enrofloxacin) must follow to comply with the European Pharmacopoeia standards. It does not state that it is for suspension product forms only. Decision of 293rd meeting: Registration Board deferred the application for dosage form clarification. Submission by the firm: The firm has submitted that the dosage form of the applied product is Oral Solution while in USP describes the monograph for Oral Suspension. The firm has requested for grant of registration with innovator's specifications. Moreover, the firm has submitted fee Rs. 5,000/- with the reply (challan number 0539489 dated 22/04/2020). **Decision: Deferred for confirmation of composition of formulation in the database of importing country.**	

Case No. 5: Import cases (Human) Form 5F

2082.	**Name, address of Applicant / Importer**	**M/s** Gene Tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi
	Details of Drug Sale License of importer	**License No:** 10725 **Address:** Gene-tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi **Validity: ***15-August-2020 **Status:** Drug License By way of Wholesale *The firm has submitted receipt for renewal of DSL dated 24/05/2020.
	Name and address of marketing authorization holder (abroad)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name, address of manufacturer(s)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Legalized CoPP (Certificate Ref. 665/5405)** 20-04-2019 by Ministry of Health and Medical Education declaring the free sale

		of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Product specific sole agency agreement is submitted.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	Alvocade Single use vial containing 3.5mg powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Bortezomib powder….3.5mg
	Pharmaceutical form of applied drug	Powder for Injection IV/Sc
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-House
	Proposed Pack size	1 vial box
	Proposed unit price	73.2 Dollars
	The status in reference regulatory authorities	Bortezomib 3.5 mg powder for solution for injection (UK)
	For generic drugs (me-too status)	Egybort injection by M/s Revive Pharma, Reg. No. 090738
	Module-II (Quality Overall Summary)	The submitted QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Laurus Labs Limited Plot no.21 Jawaharlal Nehru Pharma City, Parawada Visakhapatanma 531021 Andra Pradesh India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of	Submitted. Real time at -20ºC±5ºC for 12 months Accelerated study at 5ºC±3ºC for 6 months

	Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted comparative table summarizing results of all physico-chemical tests performed on 5 batches of applied product and one batch of the reference product i.e. Omnipaque injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 12 months.
	Evaluation by PEC:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2083.	**Name, address of Applicant / Importer**	**M/s** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad
	Details of Drug Sale License of importer	**License No:** DSL-002-ICT/2013 **Address:** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad **Address of Godown:** Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. **Validity:** 30/01/2022 **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	**Manufacturing site:** **Site responsible for batch release, primary and secondary packaging:** M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original Legalized CoPP (Certificate#. 2019-D1-0700) by Ministry of Food and Drug Safety declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s ILDONG Pharmaceutical co., ltd. Korea. Issued date: Mar. 15, 2019
	Details of letter of authorization / sole agency agreement	Authorization letter by manufacturer M/s ILDONG Pharmaceutical co., ltd. In the name of importer M/s Amgomed

		registration, sale and distribution in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	SPECSSA Tablet 250mg (Gefitinib)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Gefitinib……..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anticaner
	Reference to Finished product specifications	In house
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**IRESSA of USFDA**
	For generic drugs (me-too status)	Gefticip 250mg Tablet of M/s AJMs
	Module-II (Quality Overall Summary)	Submitted. The QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Mac chem Products (India) Pvt. Ltd. N-211/2/10. Tarapur MIDC.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time at 30°C±2°C & 65%RH±5% of 3 batches for 24 months Accelerated at 40°C±2°C & 65%RH±5% of 3 batches for 24 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation

		protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVC blister and hard foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 36 months.
	Evaluation by PEC:	
	Decsion: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2084.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16455 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 5ml contains: Paclitaxel……30mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	antineoplastic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Paclitaxel Injection 30mg/5Ml of M/s Innopharm Karachi
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25°C±2°C 60%±5% RH) 24 months and Accelerated study (40°C±2°C 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted pharmaceutical equivalence against the innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC-I:		
Decision: Deferred for clarification regarding storage conditions of stability study data of finished product which is not as per Zone IVA.		
2085.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16457 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 16.7ml contains: Paclitaxel……100mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Ebetaxel 100mg/16.7Ml Injection M/s Bio Pharma
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial

	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		
2086.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16456 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)

	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 50ml contains: Paclitaxel……300mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	DRIFEN 300MG INJECTABLE SOLUTION M/s Haji Medicine
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		

2087.	Name, address of Applicant / Importer	M/s Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	Drug License by the way of Wholesale License No: 0865 Address: Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. Validity: 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Free sale certificate no. 2017-019 issued by Neijiang Bureau of Ministry of Commerce of the people's republic of China on 27/07/2017. Eudra GMDP status checked from web dated 10-07-2019 show that competent authority of the UK confirms the following manufacturer M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China has been inspected dated 21/08/2017, it is considered that it complies with the principle and guideline of GMP laid down in Directive 2003/EC.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 3687 Dated 16-04-2019
	Details of fee submitted	Rs. 100,000/- Dated 16-04-2019
	The proposed proprietary name / brand name	Azacitidine Seacross powder for suspension for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Azacitidine……..100mg

	Pharmaceutical form of applied drug	Powder for suspension for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's 30ml glass Vial
	Proposed unit price	Price as per SRO
	The status in reference regulatory authorities	VIDAZA of Baxter Oncology GmbH 33790 Halle/Westfalen Germany
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) 6 months of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted against the innovator product VIDAZA® by M/s Colgene. As the product is intended to be administered Sc, therefore In-vitro dissolution testing at 37ºC against the innovator product is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (30ºC±2ºC 65%±5% RH) 36 months and Accelerated study (40ºC±2ºC 75%±5% RH) 6 months of 3 batches.
Evaluation by PEC: FSC issuing authority Neijiang Bureau of Ministry of Commerce of the people's republic of China which is not concern regulatory authority i.e. China Food & Drug Administration.		
Decision: Deferred for issuance of CoPP from relevant regulatory authority.		
2088.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi

	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor *the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Original Legalized CoPP (Certificate#. 2018-0070)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22424 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 50mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..50mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 50 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan

	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 50MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25°C for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: Submitted comparative dissolution profile of applied Neolymin 50mg Soft Gelatin Capsule with Neoral 25mg, Justify. (The firm has stated that the formulation of cyclosporine capsule 25mg and 50mg is proportional and the manufacturing process is the same.)		
Decision: The Board deferred the case for submission of comparative dissolution profile of the applied product against the reference product of the same strength that is 50mg.		
2089.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor *the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China

	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Original Legalized CoPP (Certificate#. 2018-0069)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer..
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22423 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 25mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..25mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 25 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan
	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 25MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical

		form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25°C for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: The seal of the submitted CoPP is not intact.		
Decision: Approved as per Import Policy for finished drugs. Firm will submit valid CoPP for further processing of case.		
2090.	Name, address of Applicant / Importer	**M/s** M/s OBS Pakistan Pvt. Ltd., C-14, Manghopir Road, S.I.T.E. Karachi
	Details of Drug Sale License of importer	**License No:** 0950 **Address:** OBS Pakistan PVt LTD Plot No. C-14, Manghopir Road Site area Karachi. **Validity**26-03-2021 **Status:** Drug License by Way of Wholesale
	Name and address of marketing authorization holder (abroad)	**Product License Holder:** Merck Sharp and Dome B.V., Waarderwg 39, 2031 BN Haarlem, the Netherlands.
	Name, address of manufacturer(s)	**Manufactured by**: Steri Pharma, LLC 429S.West street Syracuse, NY 13202, USA **Released By:** Laboratoires Merck Sharp & Dohme Chibret, Route de Marsat-Riom, 63963 Clermont Ferrand Cedex 9, France
	Name of exporting country	Netherland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2FM2-4328) by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer. Certificate Expiration Date: June 24, 2021.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted. MSD authorizes M/s OBS Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21535 Dated 22-10-2019
	Details of fee submitted	(Rs. 100,000/- Dated 22-10-2019)
	The proposed proprietary name / brand name	Zerbaxa, Powder for concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftolozane …1gm (eq. to 1.147g of ceftolozane sulfate) Tazobactam… 0.5g (eq. to 0.537g of tazobactam sodium)
	Pharmaceutical form of applied drug	Powder for concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	In-house
	Proposed Pack size	10's vials
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Ceftolozane: M/s Acs Dobfar, S.p.A (ACSD4) via Marzabotto, 1,7/9 20871 vimercate (MB) Italy. Tazobactam sodium: M/s Qilu Tianhe Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, 250105 Jinan, Shandong Province, P.R. of China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture,

		manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 5±3^{0}C and 6 months at 25^{0}C±60%RH for three batches.
Remarks of Evaluator-I: QOS of module 2 is complete but not as per WHO/Form-5F format. The firm has submitted that the name of legal entity of drug substance manufacturer (Tazobactam Sodium) has been changed from "Qilu Tianhe Pharmacetuical Co., Ltd. to "Shandong Anxin Pharmacetuical Co., Ltd. The firm has stated that the manufacturing site is not changed.Valid GMP of the manufacturer mentioning the changed name and address along with the old name and address of the API manufacturer (certificate no. IT/E/API/04/2020, issued on the basis of inspection conducted on 18-09-2019) is submitted along with the reply. Moreover, updated relevant section (2.3.s.2.1) is submitted as well. Name and address: M/s Shandong Anxin Pharmaceutical Co., Ltd (formerly Qilu Tianhe Pharmaceutical Co., Ltd) No. 10678 Wenliang Road, Dongja town, Licheng District (former No. 849 Dongja town, lichen District, Jinan Shandong, 250105, China.		
Decision: Deferred for submission of complete S part of module 2 and 3 of CTD.		
2091.	Name, address of Applicant / Importer	**M/s** Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi
	Details of Drug Sale License of importer	**Address:** Timax Life Scineces Pvt. Ltd. M-1, Fl-37, Block-B, Gulshan e Jamal Karachi **Validity:** 05/03/2021
	Name and address of marketing authorization holder (abroad)	M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570 Tandogan-ANKARA/ TURKEY
	Name, address of manufacturer(s)	M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2018/2468) issued on 28-06-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey valid until 28/06/2020.
	Details of letter of authorization / sole agency agreement	Original legalized Authorization letter from Product License Holder: M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570 Tandogan-ANKARA/ TURKEY in the name of importer M/s Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi for product MRSACIN-50mg containing lyophilized powder for IV infusion is submitted
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 42062 Dated 07-12-2018
	Details of fee submitted	(Rs. 100,000/- Dated 07-12-201)
	The proposed proprietary name / brand name	MRSACIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Lyophilized tigecycline…..50mg
	Pharmaceutical form of applied drug	Lyophilized powder for solution for IV infusion
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil 50 mg powder for solution for infusion (Belgium)
	For generic drugs (me-too status)	Tygatec 50mg Injection of M/s Safe Pharmaceuticals (Pvt) Ltd. Karachi
	Module-II (Quality Overall Summary)	submitted
	Name, address of drug substance manufacturer	M/s UNIMARK REMEDIES LIMITED 501, 5th Floor, E-Wing, Sky Park CHS Ltd., MMRDA District Centre, Oshiwara Garden Road, Off. S.V. Road, Goregaon (West) Mumbai India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted real time stability study data 25°C±2 and 60%±5 for 2 years and accelerated at 40°C±2 and 75%±5.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	The firm has submitted real time stability study data 25°C±2 and 60%±5.
Remarks of Evaluator-I: Stability study data (Real time + Accelerated) according to the conditions of Zone-IVA required.		
Decision: Deferred for submission of real time and accelerated stability data of 03 batches according to the conditions of zone IV-A.		

Case no.6: Deferred cases (import) submitted on Form 5F

2092. Nab-Xelpac Injection (Lyophilized Powder) applied by M/s Himmel Pharmaceuticals (Pvt.) Ltd Lahore

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 26966 Dated 13-12-2019 PKR: 50,000/- dated 19-03-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2	Name, address and contact details of Manufacturing site. Product License Holder & Manufacturer: M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** License to Sell drugs as a Distributor No: 0011000 0001520 valid upto 06-Feb-2020
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Nanoparticle Albumin bound Paclitaxel USP
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Nanoparticle Albumin bound Paclitaxel USP …..100mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Nab-Xelpac Injection (Lyophilized Powder)

	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Antineoplastic agents
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration IV
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price ONCOTAXEL 100MG INJECTION of M/S. PHARMEVO (PRIVATE) LIMITED,
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Abraxane 5 mg/ml powder for suspension for infusion (Netherlands)
	1.5.10	Dosage form of applied drug Injection (Lyophilized Powder) : 100mg
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.

	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. DA/6-110/2016/3677)** issued on 18-02-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited. • Copy of Product specific sole agency agreement is submitted.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted

	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30 ± 2^0C, 65±5%RH and 6 months at 40^0C±75%RH.
Decision of 293rd meeting: Deferred for submission of all commitments of module 1. Evaluation by PEC: The firm has submitted all the commitments of module I. **Decision: Approved as per Policy for inspection of Manufacturer abroad.**		

Deferred cases of COVID-19

Sr. No.	Applicant	Brand name	Composition	Dy No./fee/ date/ form	Pack size and price	GMP status	**Previous decision**
2093.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepure road Lahore	Ajicin 200mg/ 5ml for Suspension	Each 5ml reconstituted Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin…200mg	Dy.No. 12453 dated 03/06/2020Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	M/s Novamed: 22-1-2019 Good level of compliance with GMP.	**Deferred in 295th meeting for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing**

Submission by the firm:
The firm has submitted the following;

- Original contract agreement with M/s Novamed Pharma.
- No products are being manufactured on contract basis for M/s Cunningham Pharma.
- Copy of GMP certificate dated 19/04/2019 issue don the basis of inspection conducted on 01/04/2019.
- M/s Cunningham pharma has 7 approved sections.
- The firm does not have the relevant section.

Decision: Approved with USP specifications.

2094.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	Citaquine DS Tablet	Each Film Coated Tablet contains: Chloroquine phosphate……..500mg	Dy.No. 9126 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	30,000/- fee alongwith Fom-5D is required.	**Deferred in 295th meeting for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**

Submission by the firm:
The firm has submitted Form 5D and Differential fee of Rs. 30,000/- vide challan number 0792484 dated 09/06/2020.
GMP inspection dated 13-11-2019 shows that the firm was allowed resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections.

a- Sterile Section-I (General Injection)
b- Sterile Section-III (Hormonal Injection).

Decision: Approved with USP specifications.

2095.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Lopvir 200mg/ 50mg Tablet	Each Tablet Contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 9318 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5D	As per SRO	GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **submission of requisite fee for revision of formulation as per the reference product.**

Submission by the firm:
The firm has submitted;

- Fee of Rs, 5,000/- vide challan number 2039502 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following;
  Each film coated tablet contains:
  Lopinavir…..200mg
  Ritonavir…...50mg
- No product is being manufactured for M/s CSH Pharma on contract basis.
- Inspection report dated 04/05/2020, satisfactory level of GMP compliance.
- The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012.

Decision: Approved with USP specifications.

2096.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Hydroxy Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9315 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Deferred in 295th meeting for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **Submission of requisite fee for revision of formulation as per the reference product.**
Submission by the firm: The firm has submitted; • Fee of Rs, 5,000/- vide challan number 2039501 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following; Each film coated tablet contains: Hydroxychloroquine sulfate…200mg • No product is being manufactured for M/s CSH Pharma on contract basis. • Inspection report dated 04/05/2020, satisfactory level of GMP compliance. • The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012. **Decision: Approved with USP specifications.**							
2097.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Ostar 75mg Capsule	Each capsule contains: Oseltamivir as phosphate…….75 mg	Dy.No. 9316 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Registration Board referred in 295th meeting the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
Submission by the firm: The firm has submitted; • No product is being manufactured for M/s CSH Pharma on contract basis. • Inspection report dated 04/05/2020, satisfactory level of GMP compliance. • The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012. **Decision: Approved with USP specifications.**							
2098.	Deleted due to duplication						
2099.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory	Chloquine Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 7779 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption	**Deferred in 295th meeting for submission of Form 5D along with the**

	Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi					of production Form 5D along with differential fee of Rs. 30,000/- is required..	**submission of Differential fee of Rs. 30,000/-**
Submission by the firm: The firm has submitted differential fee of Rs. 30,000/- vide challan number 2025155 dated 06/05/2020 along with Form 5D. **Decision: Approved with USP specifications.**							
2100.	M/s Maple Pharmaceuticals Pvt Ltd Plot No.147, Sector 23, Korangi Industrial Area, Karachi	C-Sure Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7258 dated 14/04/2020Rs. 20,000/- dated 14-04-2020 Form 5		GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 22/12/2020. The firm has applied for plain tablet while it is approved in reference country as chewable	**Deferred in 295th meeting for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**
Submission by the firm: The firm has revised the formulation from Tablet to Chewable tablet as per the reference product along with method of manufacturing, master formula and other relevant documents with the submission of fee of Rs. 20,000/- vide challan number 2001182 dated 18/08/2020. **Decision: Approved with USP specifications.**							
2101.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Macazit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate.…500mg	Dy.No. 11497 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's as per SRO	03/05/2019 inspection dated. The panel recommended renewal of DML.	**Deferred in 295th meeting for submission of method of manufacturing.**
Submission by the firm: The firm has submitted method of manufacturing for the applied product. **Decision: Approved with USP specifications.**							
2102.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H, Sector 15 Korangi Induatrial Area Karachi	Azax 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate Eq. to Azithromycin……250mg	Dy.No. 11721 dated 21/05/2020Rs. 20,000/- (#1962153) dated 21-05-2020 Form 5	6's as per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.	**Deferred in 295th meeting for updated status of GMP from QA & LT.**
Submission by the firm: The firm has submitted last inspection report dated 09/01/2020, the report concludes that the firm was operating at acceptable level of GMP compliance. **Decision: Approved with USP specifications.**							

New Applications related to COVID-19 (Import)

2103.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 14513 Dated : 23/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 23/06/2020
	Brand Name +Dosage Form + Strength	Oseltamivir Phosphate Capsule 75mg
	Composition	Each capsule contains: Oseltamivir as Phosphate……75mg
	Finished Product Specification	USP
	Pharmacological Group	antiviral
	Shelf life	18 months
	Pack size & Demanded Price	As per SRO
	International availability	Tamiflu 75mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.
	Me-too status	Tamiflu 75mg capsule by M/s Roche.
	Stability studies	Accelerated stability study data of 03 batches for 6 months Real time stability data of 03 batches for 09months is submitted
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-19-01129 **Certified by:** Food and Drug Administration Ministry of Public health **Date of issuance:** 21/08/2019 **Free sale:** yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	Real time stability data is till 9 months,
	Decision: Deferred for confirmation of shelf life as 9 months stability data has been submitted	
2104.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand
	Type of Form	Form 5-A

	Diary No. & Date of R& I	Dy No : 13657 Dated : 15/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 15/06/2020
	Brand Name +Dosage Form + Strength	Lopinavir/Ritonavir Tablet 200/50mg
	Composition	Each film coated tablet contains: Lopinavir……200mg Ritonavir…….50mg
	Finished Product Specification	USP
	Pharmacological Group	Anti retroviral
	Shelf life	2 years
	Pack size & Demanded Price	Rs. 15,500/- per 120 tablets
	International availability	Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved.
	Me-too status	Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED, Rweg No. 62250
	Stability studies	Accelerated stability study data of 03 bathes for 6 months Real time stability data of 03 batches for 24 months is submitted as per Zone IVA
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-20-00304 **Certified by:** Food and Drug Administrtaion Ministry of Public health **Date of issuance:** 23/04/2020 **Free sale:** Yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

Case no. 01 Review of the previously presented cases

Following application was approved in 286th meeting of Registration Board held on 14th - 16th November, 2018. During subsequent processing of the said case, it has been identified that the evidence of approval of applied formulation i.e., "Each capsule contain Gabapentin …. 60mg" is not verifiable from any of the reference regulatory authorities, rather "Gabapentin 600mg tablet" is approved by US FDA. Hence the case is presented before the Board for re-consideration.

2123.	**Name and address of manufacturer / Applicant**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Brand Name +Dosage Form + Strength	Parkopentin 600mg Capsule
	Composition	Each Capsule Contains: Gabapentin…600mg
	Diary No. Date of R& I & fee	Dy.No 24892 dated 18-07-2018 Rs.20,000/- Dated 16-07-2018
	Pharmacological Group	Anti-convulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per Drap Policy
	Approval status of product in Reference Regulatory Authorities.	**USFDA Approved**
	Me-too status	**Kendis Tablets 600mg Reg # 064838**
	GMP status	The CLB in its 259th meeting held on 29th and 30th March 2018 has considered and approved the grant of DML by way of formulation. a) Tablet (General Section)

		b) Capsule (General Section) c) Liquid Syrup (General Section)
	Remarks of Evaluator	
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	

Case no. 02 Registration applications for local manufacturing of (Human) drugs

a. New cases

2124.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Merolit 1gm Injection
	Composition	"Each vial contains: Meropenem……1gm"
	Diary No. Date of R& I & fee	Dy. No 16389 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[II]	Initially form has submitted stability study reports for accelerated conditions but now the applicant has requested a sunder: "This is our product Merolit 500mg & 1gm, its me too status is available, we want to withdraw its stability and require normal approval of product."
	Decision: Deferred for consideration as per queue.	
2125.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name + Dosage Form + Strength	Merolit 500mg Injection
	Composition	"Each vial contains: Meropenem…500mg"
	Diary No. Date of R& I & fee	Dy. No 16390 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [II]	
	Decision: Deferred for consideration as per queue.	

b. Deferred cases

2126.	**Name and address of manufacturer / Applicant**	**M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name +Dosage Form + Strength	Zibix 200mg Tablet
	Composition	Each film coated Tablet Contains: Celecoxib……200mg
	Diary No. Date of R& I & fee	Dy.No.16179 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength/dosage form)	Coxia 200 mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Celebrex 200mg capsule" of M/s Upjohn UK Limited approved by MHRA of UK whereas applied formulation is of tablet dosage form. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2127.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 10mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…10mg Atorvastatin (as calcium trihydrate) …10mg"
	Diary No. Date of R& I & fee	Dy. No 28143 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Combitrol 10/10 tablet by M/s Ferozsons Labs. (Reg#050815)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (M-291)	Deferred for confirmation of valid DML status of the firm from Licensing Division.
	Firm's response	Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	

2128.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 5mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…5mg Atorvastatin (as calcium trihydrate) ……10mg"
	Diary No. Date of R& I & fee	Dy. No 28142 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Atease 5+10mg Tablet by M/s PharmEvo (Reg#050559)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Caduet tablet" of M/s PHARMACIA approved by US FDA. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	
2129.	Name and address of manufacturer / Applicant	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg"
	Diary No. Date of R& I & fee	Dy. No 771 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	070493 Prefair 500/15mg M/s Merck, Balochistan
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.

	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg
	Decision: Approved.	
2130.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/850 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg"
	Diary No. Date of R& I & fee	Dy.No 772 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	076217 Muppet 15mg/850mg Tablet M/s PPP, Karachi.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.
	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg
	Decision: Approved.	
2131	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name+Dosage Form + Strength	Azimed 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 44138 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azithromycin 250mg Capsules Unipharma (Pvt) Ltd., 071421
	GMP status	28-09-2017 and good
	Remarks of the Evaluator XIII	• Azithromycin "as" dihydrate is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Previous Decision (M-295)	Deferred for evidence of approval of relevant/required manufacturing facility and revision of formulation as per the

		innovator / reference product along with submission of fee for revision of formulation.
	Firm's response	• Firm has submitted revised master formulation in line with the reference product i.e., "Each Capsule Contains: Azithromycin as dihydrate……250mg" • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued including the section of "Capsule (general)".
	Decision: Approved as per following composition: "Each Capsule Contains: Azithromycin as dihydrate……250mg"	
2132.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 100mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….100mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 100/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 100mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting **(M-289)**. Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material

		particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1).
	Previous decision (M-295):	Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.
2133.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 200mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….200mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications (M-243): • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting (M-289). Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-**

		293).
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1)
	Previous decision (295):	Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.
	Firm's response: • As concerned of manufacturing controls for particle size of blend, we will use DPI grade API & lactose (Respitose) as an excepient. Therefore, we do not require spiral jet mill/high shear mixer to fine the material. We have arranged micronized Budesonide, formoterol fumarate and inhalation grade lactose (Respitose SV003) in our proposed formulation. • We are also providing our commitment/undertaking for arrangement/purchase of Spiral Jet Mill/high shear mixer, when our applied products have requirements of particle size reduction in future. • We have separate manufacturing facility for capsules (General) & capsules (steroidal). Our Steroidal capsule manufacturing section is also verified by DRAP Officials during their inspections. We also have separate dispensing booth for dispensing of steroidal API. • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange		

	Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly, we have also included "target delivery dose" in our product specifications.	
	Decision: Registration Board deliberated upon submission of firm and decided as under: **i. Approved the applied product considering the fact that the use of micronized DPI grade APIs does not necessitate the use of Spiral Jet Mill/high shear mixer.** **ii. The firm shall include the test of Aerodynamic particle size distribution" in the finished product specifications to ensure the required particle size of the formulation blend.** **iii. Firm shall use micronized DPI grade excipient for the applied product.** **iv. Registration letter shall be issued with following label claim:** **"Each capsule contains:** **Formoterol Fumarate (micronized) ……. 6mcg** **Budesonide (micronized) ……..… 200mcg"**	
2134.	Name and address of manufacturer / Applicant	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 120 injection
	Composition	Each vial contains: Artesunate ……. 120mg
	Diary No. Date of R& I & fee	Dy. No. 1115, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076073)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2135.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 30 injection
	Composition	Each vial contains: Artesunate ……. 30mg
	Diary No. Date of R& I & fee	Dy. No. 1118, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076072)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).

	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2136.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 60 injection
	Composition	Each vial contains: Artesunate ……. 60 mg
	Diary No. Date of R& I & fee	Dy. No. 1117, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma (Pvt) Ltd. Karachi (Reg#057719)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2137.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy. No 28456 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Previous Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019.

		• Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2138.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy. No 28455 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsule by M/s Getz Pharma (Reg#048725)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019 concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019. • Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2139.	**Name and address of manufacturer / Applicant**	**M/s. HiMedic Pharmaceutcals (Pvt) Ltd.0 Lahore**
	Brand Name +Dosage Form + Strength	Soclar Drops 50mg/ml
	Composition	Each ml Contains: Cefaclor (as monohydrate)……50mg
	Diary No. Date of R& I & fee	Dy. No.31; 26-07-2016; Rs.20,000/- (26-07-2016)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15ml; Rs. 131.66/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA as suspension dosage form
	Me-too status (with strength and dosage form)	Slate Drops 50mg/ml of M/s SAMI Pharmaceuticals (Reg.# 075939)
	GMP status	Last GMP inspection conducted on 09-08-2018
	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-285)	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.

	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 24-01-2020.
	Decision of 296th meeting: Approved with USP specifications.	
2140.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, Pakistan by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 2.25g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…2.0g Tazobactam sodium eq to Tazobactam…0.25g"
	Diary No. Date of R& I & fee	Dy.No 7048 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044142; Tazobact 2.25g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	
2141.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 4.5g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…4.0g Tazobactam sodium eq to Tazobactam…0.5g"
	Diary No. Date of R& I & fee	Dy.No 7049 dated 19-02-2019 Rs.50,000/- 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044143 Tazobact 4.5g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.

	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. Deferred Cases

2142.	**Name and address of Applicant**	**M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan**
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • Only brand name has been mentioned without label claim.

		• The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis. • Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA. • The firm submitted Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 26.09.2019.
	Previous decision	The Board in its 293rd meeting deferred the case for or changing the address of applicant in Form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Previous decision (M-295)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Remarks of Evaluator	Following reference of me-too product has been verified: "DOXYSIN WATER SOLUBLE POWDER" of M/s UNIVET PHARMACEUTICALS, RAWALPINDI. (Reg.#033256)
	Decision of 296th meeting: Approved.	

Case no. 04 Registration applications of newly granted DML or New section (Human)

a. New DML /section

M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa, has been granted approval for two new tablet sections in 274th meeting of CLB. Now the firm has applied following products for priority consideration against these two new sections.

2143.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15180: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…5mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)
	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 5mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
API Lot No.	ETG20190101
Description of Pack (Container closure	Alu-Alu blister in unit carton

system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-001	ERTab-001	ERTab-001
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

2144.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15181: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)
	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 15mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China.
API Lot No.	ETG20190101
Description of Pack	Alu-Alu blister in unit carton

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-004	ERTab-005	ERTab-006
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
1.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall

		have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
2.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
	P - PART	
3.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
4.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Registration Board deferred the applications of Ertuvia 5mg Tablet & Ertuvia 15mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
1.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance

		with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
2.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
	P - PART	
3.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
4.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

2145.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15183: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia-S 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…….5mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin……100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China		
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-007	ERTab-008	ERTab-009
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]:		

2146.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15182: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia-S 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079
Description of Pack	Alu-Alu blister in unit carton

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-010	ERTab-011	ERTab-012
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
1.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
2.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
3.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
		P - PART
4.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP

		chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
5.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Decision: Registration Board deferred the applications of Ertuvia-S 5/100 mg Tablet & Ertuvia-S 15/100 mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
1.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
2.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
3.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.

P - PART		
4.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
5.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Case no. 05 Registration applications of import cases

a. New Cases (Veterinary)

2147	**Name and address of Applicant**	**M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan**
	Detail of Drug Sale License	Address: **M/s Prix Pharmaceutica,** 26 abbot road Lahore (Godown: Plot NO. 5, Pharmacity, 30Km Multan Road Lahore. Validity: 12/06/2022`
	Name and address of manufacturer	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name and address of marketing authorization holder	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name of exporting country	**Italy**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 75 Dated 14-07-2015
	Fee including differential fee	Rs. 50,000/- Dated 10-07-2015
	Brand Name +Dosage Form + Strength	**ZOOCOLAGOGO C.M. Oral Powder**
	Composition	Each 18gm sachet contains: Rhubarb ……. 9gm Boldo leaf …….. 6gm Condurango ……. 2gm Nux vomica ……. 1gm
	Finished Product Specification	Manufacturer's specification
	Pharmacological Group	Products for alimentary tract and metabolism
	Shelf life	5 years
	Demanded Price	Decontrolled
	Pack size	1's
	International availability	Approved by Italy (Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products)
	Me-too status	N/A
	Stability studies	Firm has submitted long term (60 months) at 25+2$_o$C, 60+5%RH & accelerated (06 months) stability data at 40+ 2$_o$C, 75+ 5% RH for three batches.

	Detail of certificates attached	• **Original Legalized CoPP** **Certificate No:** 163/2018/C **Certifying Authority:** Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products **Issue Date:** 19-08-2018 **Free sale in exporting country: Yes** • **GMP of manufacturer:** Yes **GMP Certificate** The GMP certificate (No. NBF/18/2017/V) issued by Ministry of Health - General Directorate of Animal Health and Veterinary Drugs Italy, submitted by the firm and also available at EUDRA GMP database, valid upto 23-02-2020. **Sole Agency Agreement:** Firm has submitted declaration form M/s Fatro S.P.A, Italy wherein M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan has been declared as sole agent in Pakistan for their product "Zoocolagogo C.M. oral powder".
	Remarks of the Evaluator:	
	Decision: Registration Board deferred the case for following: **i. Opinion from H&OTC division regarding the classification of applied formulation.** **ii. Submission of stability data of the applied product as per Zone IV-a conditions.** **iii. Submission of valid legalized GMP certificate of the finished product manufacturer.**	

Case no. 06 Registration applications of drugs for which stability study data is submitted

a. New cases

2148.	**Name and address of manufacturer / Applicant**	**M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Jenta 80mg Injection
	Composition	Each ampoule contains: Gentamicin as sulphate ……. 80mg
	Diary No. Date of R& I & fee	Dy.No.728, 27-7-2016, Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	2 ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL GENTAMICIN 80mg/2mL Injection BP (TGA)
	Me-too status	GENXAT of Surge pharma
		Last GMP Inspection dated 03-04-2019 with conclusive remarks of acceptable cGMP compliance.
	Remarks of Evaluator	
	Decision:	

STABILITY STUDY DATA	
Drug	Jenta 80mg Injection
Name of Manufacturer	M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.
Manufacturer of API	M/s Fujian Fukang Pharmaceutical Co., Ltd., Jiangyin Industrial Estate, Fujian, China
API Lot No.	FG 1608226
Description of Pack	LDPE Ampoule

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,1,3,6 months		
Batch No.	001	002	003
Batch Size	20,000 ampoules	20,000 ampoules	20,000 ampoules
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	20-01-2017	20-01-2017	20-01-2017
No. of Batches	03		
Date of Submission	03-12-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate (Certificate#FJ20170003) issued by Germany, **valid upto 09-04-2022**
	Protocols followed for conduction of stability study and details of tests.	Yes
3.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
4.	Documents confirming import of API etc.	Copy of ADC attested invoice for Gentamicin sulfate, dated 16-12-2016.
5.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
6.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
7.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

i. Firm has submitted data for Bio-Assay analysis as per USP monograph.

ii. Firm has used LDPE ampoules as primary container closure system for applied formulation which is a semi permeable container. As per ICH guidelines for drug products packaged in semi-permeable containers the testing conditions are:

Study	Storage conditions
Long Term	30°C ± 2°C/35% RH ± 5% RH
Accelerated	40°C ± 2°C/not more than (NMT) 25% RH

iii. The firm has submitted reports of 6 months accelerated & long term stability studies, for all the above three batches of Jenta 80mg injection, the firm has derived water loss rate by applying alternate approach given in the ICH Q1A (R2) guidelines as below:

Batch No.: 001 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3808	0.04	11	3.3821	3.3814	0.06
2	3.3218	3.3208	0.06	12	3.4509	3.4499	0.09
3	3.4285	3.4280	0.03	13	3.4742	3.4737	0.04
4	3.3156	3.3143	0.07	14	3.4351	3.4343	0.07
5	3.3672	3.3661	0.06	15	3.3577	3.3570	0.06
6	3.4264	3.4255	0.05	16	3.4231	3.4222	0.08
7	3.4305	3.4301	0.02	17	3.3688	3.3684	0.04
8	3.3721	3.3706	0.08	18	3.3103	3.3097	0.05
9	3.3985	3.3979	0.03	19	3.3280	3.3277	0.03
10	3.3912	3.3897	0.08	20	3.3902	3.3893	0.08

Batch No.: 001 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3815	3.3790	0.14	11	3.3821	3.3806	0.13
2	3.3218	3.3198	0.11	12	3.4509	3.4496	0.11
3	3.4285	3.4256	0.16	13	3.4742	3.4726	0.14
4	3.3156	3.3134	0.13	14	3.4351	3.4339	0.10
5	3.3672	3.3644	0.16	15	3.3577	3.3563	0.13
6	3.4264	3.4237	0.15	16	3.4231	3.4216	0.13
7	3.4305	3.4277	0.16	17	3.3688	3.3672	0.14
8	3.3721	3.3692	0.16	18	3.3103	3.3084	0.17
9	3.3985	3.3963	0.12	19	3.3280	3.3265	0.14
10	3.3912	3.3892	0.11	20	3.3902	3.3890	0.11

Batch No.: 001 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3780	0.20	11	3.3821	3.3796	0.22
2	3.3218	3.3180	0.22	12	3.4509	3.4486	0.20
3	3.4285	3.4246	0.22	13	3.4742	3.4716	0.22
4	3.3156	3.3124	0.18	14	3.4351	3.4329	0.19
5	3.3672	3.3634	0.21	15	3.3577	3.3553	0.21
6	3.4264	3.4227	0.21	16	3.4231	3.4206	0.22
7	3.4305	3.4257	0.27	17	3.3688	3.3662	0.23
8	3.3721	3.3682	0.22	18	3.3103	3.3074	0.26
9	3.3985	3.3953	0.18	19	3.3280	3.3265	0.14
10	3.3912	3.3877	0.20	20	3.3902	3.3880	0.19

Batch No.: 002 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3942	3.3935	0.04	11	3.3924	3.3917	0.06
2	3.3861	3.3851	0.06	12	3.3891	3.3881	0.09
3	3.4025	3.4020	0.03	13	3.3642	3.3637	0.04
4	3.3814	3.3801	0.07	14	3.3904	3.3896	0.07
5	3.3881	3.3870	0.06	15	3.3891	3.3884	0.06
6	3.3790	3.3781	0.05	16	3.3947	3.3938	0.08
7	3.3953	3.3949	0.02	17	3.3982	3.3978	0.04
8	3.3684	3.3669	0.08	18	3.3862	3.3856	0.05
9	3.3943	3.3937	0.03	19	3.3944	3.3941	0.03
10	3.3769	3.3754	0.08	20	3.3983	3.3974	0.08

Batch No.: 002 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3912	3.3887	0.14	11	3.3924	3.3909	0.13
2	3.3704	3.3684	0.11	12	3.3891	3.3878	0.12
3	3.3845	3.3816	0.16	13	3.3642	3.3626	0.14
4	3.3905	3.3883	0.12	14	3.9904	3.9892	0.09
5	3.3887	3.3859	0.16	15	3.3891	3.3877	0.12
6	3.3781	3.3754	0.15	16	3.3947	3.3932	0.13
7	3.3826	3.3798	0.16	17	3.3982	3.3966	0.14
8	3.3942	3.3913	0.16	18	3.3862	3.3843	0.17
9	3.3807	3.3785	0.12	19	3.3944	3.3929	0.13
10	3.3841	3.3821	0.11	20	3.3983	3.3971	0.11

Batch No.: 002 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3912	3.3877	0.20	11	3.3924	3.3899	0.22
2	3.3704	3.3666	0.21	12	3.3891	3.3868	0.20
3	3.3845	3.3806	0.22	13	3.3642	3.3616	0.23
4	3.3905	3.3875	0.17	14	3.9904	3.9882	0.17
5	3.3887	3.3849	0.21	15	3.3891	3.3867	0.21
6	3.3781	3.3744	0.21	16	3.3947	3.3922	0.22
7	3.3826	3.3787	0.22	17	3.3982	3.3956	0.23
8	3.3942	3.3903	0.22	18	3.3862	3.3842	0.18
9	3.3807	3.3775	0.18	19	3.3944	3.3929	0.13
10	3.3841	3.3806	0.20	20	3.3983	3.3961	0.19

Batch No.: 003 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3845	0.04	11	3.3874	3.3867	0.06
2	3.3945	3.3935	0.06	12	3.3907	3.3897	0.09
3	3.3793	3.3788	0.03	13	3.3791	3.3786	0.04
4	3.3824	3.3811	0.07	14	3.3953	3.3945	0.07
5	3.3948	3.3937	0.06	15	3.3778	3.3771	0.06
6	3.3887	3.3878	0.05	16	3.3827	3.3818	0.08
7	3.3796	3.3792	0.02	17	3.3809	3.3805	0.04
8	3.3821	3.3806	0.08	18	3.3945	3.3939	0.05
9	3.3943	3.3937	0.03	19	3.3824	3.3821	0.03
10	3.3844	3.3829	0.08	20	3.3798	3.3789	0.08

Batch No.: 003 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3852	3.3827	0.14	11	3.3874	3.3859	0.13
2	3.3945	3.3925	0.11	12	3.3907	3.3894	0.12
3	3.3793	3.3764	0.16	13	3.3791	3.3775	0.14
4	3.3824	3.3802	0.12	14	3.3953	3.3941	0.11
5	3.3948	3.3920	0.16	15	3.3778	3.3764	0.12
6	3.3887	3.3860	0.15	16	3.3827	3.3812	0.13
7	3.3796	3.3768	0.16	17	3.3809	3.3793	0.14
8	3.3821	3.3792	0.16	18	3.3945	3.3926	0.17
9	3.3943	3.3921	0.12	19	3.3824	3.3809	0.13
10	3.3844	3.3824	0.11	20	3.3798	3.3786	0.11

Batch No.: 003 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3817	0.20	11	3.3874	3.3849	0.22
2	3.3945	3.3907	0.21	12	3.3907	3.3884	0.20
3	3.3793	3.3754	0.22	13	3.3791	3.3765	0.23
4	3.3824	3.3792	0.18	14	3.3953	3.3931	0.19
5	3.3948	3.3910	0.21	15	3.3778	3.3754	0.21
6	3.3887	3.3850	0.21	16	3.3827	3.3802	0.22
7	3.3796	3.3748	0.27	17	3.3809	3.3783	0.23
8	3.3821	3.3782	0.22	18	3.3945	3.3916	0.26
9	3.3943	3.3911	0.18	19	3.3824	3.3807	0.15
10	3.3844	3.3809	0.20	20	3.3798	3.3776	0.20

Moreover firm has submitted Container Qualification Studies for Low Density Polyethylene (LDPE), as per USP. The submitted studies make following declarations:

- Material pass the test describe in European Pharmacopoeia.
- Material pass the test describe in USP.
- LDPELE6609 PH has FDA drug master file number DMF 17927 (24086 ex Porvoo)
- PCSIR test reports for extractable metals concluded that No Extractable was found in LDPE sample tested as per USP<661.1>.
- Sample analysed as per USP <661.2> and found results within the USP specification.

Decision: Registration Board deliberated the case in detail and considering the submitted stability data "Container qualification studies", the Board decided to approve Jenta 80mg injection (Gentamicin)", of M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.

b. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2149.	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Aglizon 10mg Tablet Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…10mg (In-house specifications)	Form-5D Dy. No: 19554 Dated 30.10.2017 Rs.50,000/- As per SRO (1x10's, 2x10's, 3x10's)	FORXIGA dapagliflozin (as propanediol monohydrate) 10 mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA	
Drug	Aglizon 10mg Tablet
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)

Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4341)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>➢ <u>Declaration by WIS Pharmtec Co. Ltd, China</u>
The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information.
Batch No.: DGF20180101
Mfg Date: 05.01.2018
➢ <u>Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China</u>
Invoice No. WIS180047
Quantity imported: 0.22 Kg
Date of import: 28.03.2018
ADC Attestation Date: 14.05.2018
Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
Batch No.: DGF20180101</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No. The firm submitted that these were in minute quantity and free of cost.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, China for API valid till 18.08.2019, issued by China FDA.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Shangai Pharma Group Changzhou.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of reference standard and impurity A have been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of three qualified staff involved in product development. One of them is intermediate passed, who is assistant officer production</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
a. Development protocol.
b. Stability Study Protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>TF001</td><td>05-2018</td><td>1000/992</td></tr>
<tr><td>TF002</td><td>05-2018</td><td>1000/988</td></tr>
<tr><td>TF003</td><td>05-2018</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>TF001</td><td>1000</td><td>992</td><td>480</td></tr>
<tr><td>TF002</td><td>1000</td><td>988</td><td>540</td></tr>
</table></td></tr>
</table>

		TF003	1000	984	540
QA / QC DATA					
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Yes			
13.	Method used for analysis of API along with COA.	The firm has applied supplier's method for analysis of API and has submitted their analytical reports, raw data sheets & relevant chromatograms.			
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	• The firm has submitted photocopy of Finished Product specification & Test method. • Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)			
15.	Reports of stability studies of API from manufacturer.	The firm has submitted copies of reports of 06 Months Accelerated and 18 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API. **The firm has also submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API, wherein impurity A has not been tested.**			
16.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.			
17.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation.			
18.	Record of comparative dissolution data.	pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8. **Feature** / **Reference product** Brand name: Forxiga Tab. 10mg Batch No.: NX685 Mfg. date: NIL			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.			
Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.					
Evaluation by PEC: Firm has now submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.					
Decision:					
Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability GMP Inspection Report Date & Remarks**	
2150.	M/s Helix Pharma (Pvt.) Ltd.,	Aglizon 5mg Tablet	Form-5D Dy. No: 19540	FORXIGA dapagliflozin (as	

	Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…5mg (In-house specifications)	Dated 30.10.2017 Rs.50,000/- (**Duplicate dossier)** As per SRO (1x10's, 2x10's, 3x10's)	propanediol monohydrate) 5mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA			
Drug	Aglizon 5mg Tablet		
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700		
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.		
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4342)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.

	manufacturer issued by regulatory authority of country of origin.	
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	➢ **Declaration by WIS Pharmtec Co. Ltd, China** The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information. Batch No.: DGF20180101 Mfg Date: 05.01.2018 ➢ **Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China** Invoice No. WIS180047 Quantity imported: 0.22 Kg Date of import: 28.03.2018 ADC Attestation Date: 14.05.2018 Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China. Batch No.: DGF20180101

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Yes</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, China for API valid till 18.08.2019, issued by China FDA.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Shangai Pharma Group Changzhou.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of reference standard and impurity A have been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of three qualified staff involved in product development. One of them is intermediate passed, who is assistant officer production</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
c. Development protocol.
d. Stability Study Protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>TF001</td><td>05-2018</td><td>1000/986</td></tr>
<tr><td>TF002</td><td>05-2018</td><td>1000/990</td></tr>
<tr><td>TF003</td><td>05-2018</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>TF001</td><td>1000</td><td>986</td><td>480</td></tr>
<tr><td>TF002</td><td>1000</td><td>990</td><td>570</td></tr>
<tr><td>TF003</td><td>1000</td><td>984</td><td>540</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has applied supplier’s method for analysis of API and has submitted their analytical reports, raw data sheets & relevant chromatograms.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• The firm has submitted photocopy of Finished Product specification & Test method.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copies of reports of 06 Months Accelerated and 18 Months Real Time Stability Study (30^{o}C$\pm$2 ^{o}C, 65$\pm$5%) Data of 03 Batches of API.</td></tr>
</table>

<table>
<tr><td></td><td></td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API, wherein impurity A has not been tested.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is similar to innovator's product formulation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
<tr><td>Brand name</td><td>Forxiga Tab. 5mg</td></tr>
<tr><td>Batch No.</td><td>V832F</td></tr>
<tr><td>Mfg. date</td><td>NIL</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for complete stability studies analysis of three batches.</td></tr>
</table>

Remarks of Evaluator:

<table>
<tr><th>Shortcomings communicated</th><th>Response by the firm</th></tr>
<tr><td>The testing/analysis method of API is different from that of manufacturer. Justify.</td><td>90% Tests inclusive of critical tests, i.e ; Assay, Solubility, Related Substance, Clarity, Water content etc. all are comparative / present in Helix's Testing protocols same as supplier. However, test i.e; particle size is for information only & residual solvent (OVI) would be performed in future once the Gas Chromatography is purchased by Quality Control department. However, as per COA, the firm only performed description, identification water content, residue on ignition and assay with in-house claims, and the limits are as per specifications of APi manufacturer.
<table>
<tr><td></td><td>API manufacturer</td><td>FPP manufacturer</td></tr>
<tr><td>Column Condition</td><td>Agilent Zorbax SB-C18 (240mm x 4.6mm x 5 micron or equivalent)</td><td>ODS (150mm x 4.6mm x 5 micron)</td></tr>
</table></td></tr>
<tr><td>The peaks at approx. 1.19, 1.31, 1.50 and 3.73 (RT) are present in the chromatogram of initial assay, but not in that of standard. Justify/clarify.</td><td>The extra small peaks in chromatogram of assay sample is due to presence of excipients which are used in the formulation whereas no extra small peak in chromatogram of standard as the standard contains only pure active ingredient.</td></tr>
<tr><td>The innovator product has time of 15 minutes for dissolution test as per pharmacology and biopharmaceutics review. You have set it 30 minutes. Justify.</td><td>We have formulated our applied product "Aglizon Tablets (Dapagliflozin)" as film coated tablets & as per USP , disintegration time for film coated tablet is NMT 30 minutes for in-vitro test. We have performed In-vitro test not in–vivo.</td></tr>
<tr><td>Tailing factors and theoretical plates are missing in the chromatogram of API and finished product (assay, dissolution and stability data).</td><td>The firm did not submit the same.</td></tr>
</table>

In comparative dissolution profile, justify the use 06 tablets instead of 12 tablets, and the peaks in the chromatograms of samples, which are not present in those of standard.	Please note that the comparative dissolution profile (CDP) of newly applied molecules was carried out in the past by using 06 units. However, we assure you to conduct CDP by using 12 units each of reference and sample product in future & for the same we are in-process to purchase 12 to 14 units dissolution apparatus.
You have not performed drug-excipients compatibility study by submitting that stated composition of developed product is similar to innovator's product formulation. However, you have added talc powder in your formulation, which is not used in the innovator's product. Justify/clarify.	Please note that the Innovator used Talc as excipient in coating process & in our formulation, Talc is used as a Lubricant agent to improve the flow property in granulation stage. This is an inert material which do not have any therapeutic effect & is the part of formulation either used in granulation or coating process. We are enclosing herewith the reference page from Handbook of Pharmaceutical Excipients for Role of Talc for your ready reference in Annex – X.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC: Firm has submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.

Decision: Registration Board decided to approve registration of "Aglizon 5mg Tablet (Dapagliflozin 5mg) and Aglizon 10mg Tablet (Dapagliflozin 10mg) by M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2151.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 90mg Each film-coated tablet contains: Etoricoxib…90mg (Innovator's specifications)	Form-5 Dy. No: 15706 Dated 07.03.2018 Rs.20,000/- As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were

				advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA			
Drug	Etory Tablet 90mg		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura		
Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)

7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information. Batch No.: ACE 01319 Mfg Date: January, 2018 ➢ **Details of ADC attested commercial Invoice** Invoice No. KPLEXP/156/18-19 Quantity imported: 25 Kg Date of import: 22.01.2019 ADC Attestation Date: 30.01.2019 Manufacturer: NOT MENTIONED Batch No.: ACE 01319
3.	Documents for the procurement of reference standard and impurity standards.	No. but CoA of working standard, impurity I and impurity II are attached
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.
5.	Mechanism for Vendor pre-qualification	➢ The firm has submitted Vendor evaluation Form. Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.
7.	Documents for the procurement of excipients used in product development?	Yes
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted list of three qualified staff involved in product development.

Production Data

<table>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
a. Development protocol.
b. Stability Study Protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/790</td></tr>
<tr><td>ETR-PB-010001</td><td>02-2019</td><td>1000/806</td></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>790</td><td>430</td></tr>
<tr><td>ETR-PB-010001</td><td>1000</td><td>806</td><td>440</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>984</td><td>430</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has referred to analytical method of the API manufacturer.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Only method for dissolution and HPLC assay.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30ºC±2 ºC, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is qualitatively similar to innovator’s product formulation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
<tr><td>Brand name</td><td>Etoricoxib Tablet 90mg</td></tr>
<tr><td>Batch No.</td><td>1805005040</td></tr>
<tr><td>Exp. date</td><td>02.2020</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Yes</td></tr>
</table>

Remarks of Evaluator:

Shortcomings communicated	Response by the firm
The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.	In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8 As per PAR 85% are results, not limits. Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.
The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.

As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.
You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.
The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2152.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 120mg Each film-coated tablet contains: Etoricoxib…..120mg (Innovator's specifications)	Form-5 Dy. No 15707 dated 07-03-2019 Rs20,000/- Dated 06-03-2019As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition

				of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA			
Drug	Etory Tablet 120mg		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura		
Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information. Batch No.: ACE 01319 Mfg Date: January, 2018 ➢ **Details of ADC attested commercial Invoice** Invoice No. KPLEXP/156/18-19 Quantity imported: 25 Kg Date of import: 22.01.2019 ADC Attestation Date: 30.01.2019 Manufacturer: NOT MENTIONED Batch No.: ACE 01319
3.	Documents for the procurement of reference standard and impurity standards.	No. but CoA of working standard, impurity I and impurity II are attached
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.
5.	Mechanism for Vendor pre-qualification	➢ The firm has submitted Vendor evaluation Form. Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.

<table>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted list of three qualified staff involved in product development.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
a. Development protocol.
b. Stability Study Protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/790</td></tr>
<tr><td>ETR-PB-010001</td><td>02-2019</td><td>1000/806</td></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>790</td><td>430</td></tr>
<tr><td>ETR-PB-010001</td><td>1000</td><td>806</td><td>440</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>984</td><td>430</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>No, only method for HPLC assay.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Only method for dissolution and HPLC assay.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30ºC±2 ºC, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is qualitatively similar to innovator’s product formulation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
</table></td></tr>
</table>

			Brand name: Arcoxia tablet 120mg Batch No.: 1805005040 Exp. date: 02.2020
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes	

Remarks of Evaluator:

Shortcomings communicated	Response by the firm
The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.	In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8 As per PAR 85% are results, not limits. Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.
The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.

As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.
You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.
The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Response by Firm: Firm has submitted stability studies at both accelerated and long term conditions with revised specifications of Dissolution i.e., "NLT 85% within 15 minutes" at initial and one month time point. Details are as follows:

Etory 90 mg tablet:

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	96.26%
			ETR-TB-010002	95.57%	97.96%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	99.27%
			ETR-TB-010002	95.57%	98.81%

Etory 120mg tablet

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.82%
			ETR-TB-011002	100.16%	99.43%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.06%
			ETR-TB-011002	100.16%	100.55%

Decision: Registration Board decided to approve registration of "Etory Tablet 90mg (Etoricoxib) and Etory Tablet 120mg (Etoricoxib) by M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2153.	M/s. Macter International Limited, F-216, S.I.T.E, Karachi.	Vireof-N 25mg Tablets. Each film coated tablet contains: Tenofovir alafenamide (as fumarate)… 25mg	Duplicate dossier	Approved in US-FDA The firm was granted GMP certificate based on inspection conducted on 14-03-2017.

STABILITY STUDY DATA	
Drug	Vireof-N 25mg Tablets.

Name of Manufacturer	M/s. Macter International Limited, F-216, S.I.T.E, Karachi		
Manufacturer of API	Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai.		
API Lot No.	DBH251-B15A-180802		
Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1, 3,6 (month) Real Time: 0,1, 3,6 (month)		
Batch No.	001P	002P	003P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	Sep- 2018	Sep- 2018	Sep- 2018
No. of Batches	03		
Date of Submission	15-04-19 (Dy. No. 3603)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted the following: **Copy of COA** **From**:Shengai Desano Chemical Pharmaceuticals**Batch No**: DBH251-B15A-180802
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: Copy of GMP Certificate: **Certificate No:** SH2017046 **Issued To**: Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai. **Issued ON**: 04-12-2017 **Valid Till**: 3-12-2022 **Issued By**: China Food & Drug Administration.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted Coy of Commercial invoice attested by ADC on 27-08-18 having following information on it: **Invoice Number**: DL-Y-2018-0208 **Manufacturer of API**: Desano Limited. No. 1479, Zhangheng Road, Zhangliang Hi- Tech Park, Shanghai 201203, China. Tenofovir Alafenamide Fumarate API: 1kg Tenofovir Alafenamide Fumarate API W/S: 4g

		Impurity 1: 100mg Fumaric acid: 100mg Impurity 2: 100mg
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Vireof-N Tablet 25mg (TenofovirAlafenamide Fumarate) Tablets by M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 14th Nov, 2019.
Investigation Date and Time: 18th December, 2019.
Investigation Site: M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Macter International Ltd., F-216, S.I.T.E, Karachi for registration of Vireof-N Tablet 25mg (Tenofovir Alafenamide Fumarate) Tablets. PE&R Division considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and also advised to verify:

"Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM".

Composition of Panel:

1. Prof. Dr. Ghulam Sarwar, ex-member Registration Board, Dean faculty of Pharmacy, Jinnah University for Women, Karachi.
2. Dr. Affan Ali Qureshi, Assistant Director (CDL) DRAP, Karachi.
3. Dr. Kirshan Das, Assistant Director DRAP Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

S. No.	Question	Observation
1.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate API including approval from DRAP?	The firm has imported 1Kg Tenofovir Alafenamide Fumarate (API) from Shanghai Desano Chemical Pharmaceutical Co., Ltd.)vide invoice No. DL-Y-2018-0208 dated: 27.08. 2018. There is proper approval from DRAP Karachi Form 6 (2440-17).
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer of API is the vendor evaluation process based on audit and other criteria like manufacturer GMP status, DMF source etc.
3.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate reference standard and impurity standards?	The firm has imported Tenofovir Alafenamide Fumarate working standard and two impurities standards from the API manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has Certificate of Analysis of API, working standard of API and impurities standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificates for API manufacturer issued by China Food & Drugs Administration valid till 03/12/2022.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method of testing.
7.	Do you have stability studies reports on APIs?	The firm has stability studies report on API (Tenofovir Alafenamide Fumarate) conducted by API manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of API has performed the stability studies as per SIM method. The process related impurities and degradation product ie. Impurity I have been observed.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API (Tenofovir Alafenamide Fumarate) working standard and impurity standard.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Microcrystalline cellulose, Lactose Monohydrate ,Croscarmellose sodium, Magnesium stearate
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records for the excipients used.
14.	Do you have written and authorized protocols for the development of Tenofovir Alafenamide Fumarate Tablets?	The firm has written and authorized protocol for the development Tenofovir Alafenamide Fumarate Vireof-N tablets 25mg.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug Excipient compatibility studies as composition of their product is similar to that of innovator product (VEMLIDY tablets 25mgfrom GILEAD Ontario Canada.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of their product with VEMLIDY 25mg batch # CBNKMD of GILEAD and found comparable to the innovator product.

<table>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with requisite manufacturing, storage and analysis facilities.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipments available in product development section for development Tenofovir Alafenamide Fumarate Tablets?</td><td>The firm has all the necessary equipment available in product development section for the development of Tenofovir Alafenamide Fumarate tablets now, however, the product in question was manufactured in routine production area.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipments in product development section and production area are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff in PD section with proper knowledge and training in Product Development including 04 Pharmacists 05 MSc Chemistry and 01 M.Phil.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Tenofovir Alafenamide Fumarate Tablets required?</td><td>The firm has manufactured three stability batches as follows;
Tenofovir Alafenamide Fumarate 25mg tablets:
<table>
<tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr>
<tr><td>1</td><td>001P</td><td>5000</td></tr>
<tr><td>2</td><td>002P</td><td>5000</td></tr>
<tr><td>3</td><td>003P</td><td>5000</td></tr>
</table>
The tablets are packed in Alu Alu blisters with pack size 3 x 10’s.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of tablets required per testing frequency and number of testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete records of production of stability batches. All log books are properly maintained.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for the stability testing of Tenofovir Alafenamide Fumarate tablets.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method for testing of stability batches of finish product i.e. Tenofovir Alafenamide Fumarate tablets based on the API method of testing provided by the API manufacturer.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has developed and validated method based on API manufacturer for testing of finished product, so method transfer studies were required.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir Alafenamide Fumarate and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API (Tenofovir Alafenamide Fumarate) and the finished drug Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of analysis is stability indicating as evidence by forced degradation studies and spiking studies of the two major impurities.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR compliant as per record available with the firm.</td></tr>
</table>

31.	Can you show Audit trail reports on Tenofovir Alafenamide Fumarate testing?	Audit Trail on the testing reports on Tenofovir Alafenamide Fumarate API and Vireof-N tablets 25mg is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has only remaining quantities of stability batches kept on real-time stability testing.
33.	Do you have stability batches kept on stability testing?	The firm has three lab scale batches kept on stability studies for real time stability testing. Currently 12 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Tenofovir Alafenamide Fumarate Tablets production and analysis?	The firm has valid calibration status for the equipment used in Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system for stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipments, personnel and utilities are GMP compliant.
37.	Any other query raised by PE&R Division: Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM.	As per firm they have adopted Dissolution method as recommended by US-FDA. The medium is 50 mM Sodium Acetate buffer pH 4.5, Apparatus is USP type II, RPM is 75 which are same as recommended by USFDA. The sampling time is 30 mins which is the maximum time point mentioned on the website of USFDA under dissolution data, however the NDA document of VEMLIDY shows the sampling time to be 15 mins. The firm states that F2 was calculated in CDP at 10 mins because the drug was dissolved more than 90% within 5 mins which shows the formulation complies with innovator as well as US-FDA recommendation. The firm has also performed dissolution testing on an additional time point of 15 month of stability studies and observed the result at 15 minutes and found more than 90% release, which complies with innovator and US-FDA recommendations.

Conclusions:

5. On the basis of risk based approach the genuineness / authenticity of stability data including dissolution method submitted by the firm for registration of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg is verifiable satisfactory level.
6. The related manufacturing area, equipments, personnel and utilities are GMP compliant and well suited for the manufacturing of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg.
7. The case is submitted before Registration Board for decision please.

Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Sr. No.	Deferred for :	Submitted following:
1.	Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15	Applicant has submitted stability studies data for following three batches at following time points: **Batches:** Batch No: P004, P005, P006 **Testing Frequency:**

	minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.	Initial: 1 month: real time plus accelerated. Sampling Time: 15 minutes Drug release at 15 minute sampling interval: Above 90% for all trials at Ist month, as per data submitted by the firm. However data submitted by the firm is in dates before the meeting was carried out & decision of the case was made.

Decision of 295th meeting: Deferred for clarification since the dissolution testing at 15 minutes time point for 2 batches was carried out before the date of conduction of 293rd meeting of Registration Board.

Firm's response: We would like to clarify that the new batches 004P, 005P & 006P were manufactured on 20th December, 2019 immediately after the Product specific Panel inspection held on 17th, December, 2019 on behalf of detailed discussion with panel members. We are also enclosing copy of Form-06 & consumption report of API (for your ready reference). Also it is our usual practice to perform product development activities before launching of the product. We hope that the above justification will be sufficient to clarify the situation.

Decision: Registration Board decided to approve registration of "Vireof-N 25mg Tablets (Tenofovir alafenamide (as fumarate)) by M/s. Macter International Limited, F-216, S.I.T.E, Karachi. Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

c. Verification of stability study data

2154.	**Name and address of manufacturer / Applicant**	**"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"**
	Brand Name +Dosage Form + Strength	Boschofen 400mg Infusion
	Composition	"Each 100ml Vial Contains: Ibuprofen……400mg"
	Diary No. Date of R& I & fee	Dy. No 12247 dated 03-04-2018 Rs.20,000/- Dated 28-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Inbufin infusion of M/s Searle IV solutions (Reg.#094023)
	GMP status	GMP inspection dated 03-12-2018 concluding acceptable level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Boschofen 400mg Infusion
Name of Manufacturer	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
Manufacturer of API	Ibuprofen: M/s Pharmagen Ltd., Lahore, Pakistan.
API Lot No.	00510211/001/2018
Description of Pack (Container closure system)	Transparent glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	TR-BFI-02	TR-BFI-03	TR-BFI-04
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		
Date of Submission	06-05-2019 (Dy. No. 5265)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate for M/s Pharmagen Ltd. Lahore, issued on the basis of inspection conducted on 08-01-2019
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	--
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Boschofen 400mg/100ml (Ibuprofen) Infusion by M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 26th, December, 2019.
Investigation Date and Time: 8th July, 2020 (Afternoon).
Investigation Site: Factory premises of M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Background:
Chairman Registration Board considered the applications of M/s Bosch Pharmaceutical, Bosch House 221, Sector 23, Korangi Industrial Area, Karachi for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

7. Dr. Rafeeq Alam Khan, Meritorious Professor, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
8. Dr. Sanam Kausar Jahan, Assistant Director, CDL, DRAP, Karachi.
9. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

S. No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Firm has procured 0.4kg Ibuprofen from M/S Pharmagen ,Lahore
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which includes GMP Status, provision of DMF, reference standard, impurity standards etc.
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	The firm has obtained API reference standard from API manufacturer.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs and working standards
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided GMP certificate issued by Drug Regulatory Authority of Pakistan.
Q.No.6	Do you use API manufacturer method of testing for testing API?	The firm has used the manufacturer method of testing of API to carryout analysis.
Q.No.7	Do you have stability studies reports on API?	The firm has stability studies reports from API manufacturer conducted on 03 batches for accelerated and real time condition.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability data of API provided by manufacturer is stability indicating and degradation products has been quantified.
Q.No.9	Do you have method for quantifying the impurities in the API?	The firm has used the analysis method provided by the manufacturer of API for quantification of impurities in API.
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had arranged 0.4kg of Ibuprofen API out of which 0.07 kg was still available in firm .Remaining quantities of working standard and impurity standards were also available.
Q.No.11	Have you used pharmaceutical grade excipients?	The firm used pharmaceutical grade excipients.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm has proper documents for import of the used excipients.
Q.No.13	Do you have test reports and other records on the excipients used?	The firm has Analytical reports for all excipients used in product development of Boschofen infusion.
Q.No.14	Do you have written and authorized protocols for the development of applied product?	The firm had written and authorized protocol for development of Boschofen infusion .
Q.No.15	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator's product and also stability studies have not shown any incompatibility or significant degradation.

Q.No.16	Have you performed comparative dissolution studies?	Not Applicable.
Q.No.17	Do you have product development (R&D) section	The firm has dedicated area for product development.
Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	The firm has necessary equipment for manufacturing of stability batches.
Q.No.19	Are the equipments in product development section qualified?	All equipment in product development section is qualified.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance /calibration plan for equipment in product development section and maintenance /calibration are carried out accordingly.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff in product development section with relevant work experience.
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	Firm has manufactured three stability batches for the stability studies of Boschofen infusion. Batch No : TR-BFI-02 Batch No : TR-BFI-03 Batch No : TR-BFI-04
Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of vials per testing and the number of vials required for whole stability testing.
Q.No.24	Do you have complete record of production of stability batches?	The firm has complete record for manufacturing of three batches of Boschofen Infusion.
Q.No.25	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of stability batches.
Q.No.26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated the method for the testing of Boschofen infusion.
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has complete record of qualification of equipment's /instruments used for test and analysis of API and Boschofen infusion .
Q.No.29	Is your method of analysis stability indicating?	The method of analysis for finished product is stability indicating .
Q.No.30	Is your HPLC software is 21CFR compliant? (Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.))	The HPLC used for analysis of stability batches is Water e2650 with auto sampler and gradient system and it was 21CFR compliant as per record available with firm.

Q.No.31	Can you show Audit Trail reports on stability studies testing?	The firm has demonstrated the audit trail reports for the data submitted for Boschofen infusion.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	The firm had some remaining quantities of stability batches.
Q.No.33	Do you have stability batches kept on stability testing?	The firm has completed accelerated studies whereas, samples are kept for real time stability studies.
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	The firm has valid calibration status for all the equipment /instruments used in production and analysis of the Boschofen infusion .
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	The firm has two separate Stability chambers for Real time and accelerated studies which are equipped with data loggers.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area ,Equipment ,personnel and utilities can be rated as cGMP compliant

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Boshofen 400mg/100ml Infusion.

Decision: Registration Board decided to approve registration of "Boschofen 400mg Infusion (Ibuprofen) by M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

2155.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5738: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/850 Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's,14's, 20's, 28's, & 30's
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/850mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/850mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted comparative dissolution profile of applied product against the reference product, instead firm has submitted CDP data for the higher strength i.e., Xiga-met 5/1000 against the reference product Xigduo.

STABILITY STUDY DATA	
Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	XMA-T5-19	XMA-T6-19	XMA-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

2156.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5739: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/1000 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's,14's, 20's, 28's, & 30's
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/1000mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/1000mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution profile of applied product against the reference product, Xigduo (batch# X1888A) in three buffers i.e., pH 1.2, pH 4.5 & pH 6.8 with acceptable value of f2 factor.
STABILITY STUDY DATA		

Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India		
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	XMB-T5-19	XMB-T6-19	XMB-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Xiga-Met 5/1000 Tablet & Xiga-Met 5/850 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.

Date of Inspection	2nd – 3rd July, 2020
Purpose of Inspection	Verification of authenticity of stability data for purpose of registration of drugs with reference DRAP's letter no. F.1-2/2020-PEC dated 22-04-2020.
Name of Inspector	01. Dr. Muzammal Waheed Director, DTL, Faisalabad. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Hafiz Ahsan Assistant Director, DRAP, Islamabad.

Q. No.	Contents	Remarks
1.	Do you have documents confirming the import of Dapagliflozin Propanediol Monohydrate and Metformin HCl including approval from DRAP?	**Dapagliflozin Propanediol Monohydrate:** The firm has imported Dapagliflozin Propanediol Monohydrate raw material vide invoice no. HN190124-C dated 24-01-2019 from M/s. Fuxin Long Rui Pharmaceutical Co., Ltd., China and got DRAP approval vide no. 1757/2019/DRAP dated 01-02-2019. **Metformin Hydrochloride:** The firm has imported Metformin HCl raw material vide invoice no. 92002215 dated 10-12-2018 from M/s. Wanbury Ltd., India and got DRAP approval vide no. 16536/2018/DRAP dated 19-12-2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm selected API manufacturers based on their vendor evaluation mechanism.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Dapagliflozin Propanediol Monohydrate working standard from API supplier dated 27-06-2019. The firm imported Metformin HCl working standard and impurity standard (Metformin HCl Compound A) from API supplier dated 28-05-2019.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	**Dapagliflozin Propanediol Monohydrate:** The firm has certificates of analysis for API and working standard. **Metformin HCl:** The firm has certificates of analysis for API, working standard and impurity standard.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	**Dapagliflozin Propanediol Monohydrate**: The firm has valid GMP Certificate of M/s. Fuxin Long Rui, China issued by Fuxin Food & Drugs Administration, China valid till 27-09-2020.

		Metformin HCl: The firm has valid GMP Certificate of M/s. Wanbury Ltd., India issued by Directorate of Drugs Control Administration, Andhra Pradesh valid till 06-02-2022.
6.	Do you use API manufacturer method of testing for testing APIs?	The firm has used API manufacturer's method of testing. *Moreover, the firm was advised to develop method transfer protocol for testing APIs.*
7.	Do you have stability studies reports on APIs?	The firm had stability studies reports of APIs from API manufacturer: **Dapagliflozin Propanediol Monohydrate**: Accelerated (40ºC±2ºC/RH75%±5%) –6 months Real time (30ºC±2ºC/RH65%±5%) – 24 months **Metformin HCl:** Accelerated (40ºC±2ºC/RH75%±5%)– 6 months Real time (30ºC±2ºC/RH75%±5%) – 60 months
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer had performed stability as per SIM method and Metformin HCl Compound A impurity had been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm had testing method to quantify Metformin HCl Compound A impurity as provided by API manufacturer.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Nil.
11	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Avicel pH 102, Klucel EXF, Polyvinylpyrolidone, Aerosil 200, Magnesium stearate, Opadry AMB purple (88A200006) and Opadry white (85G28725).
12	Do you have documents confirming the import of the used excipients?	The firm had necessary documents confirming the import of the used excipients.
13	Do you have test reports and other records on the excipients used?	The firm had certificates of analysis of the excipients used.
14	Do you have written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?	The firm had written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.
15	Have you performed Drug-excipient compatibility studies?	The firm had performed drug-excipient compatibility studies under stress conditions of 60ºC ± 2ºC / RH 75% ± 5%.
16	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Xiga-Met 5/1000 Tablet with Xigduo 5/1000 Tablet, manufactured by M/s. AstraZeneca, USA using paddle apparatus at 100rpm in 900ml of the following dissolution mediums: 1. HCl buffer 2. Acetate buffer 3. Phosphate buffer

<table>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm had product development (R&D) section.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?</td><td>Product development section has necessary equipment to develop Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section were qualified however, the firm was advised to perform qualifications of equipment from authorized bodies.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Yes.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet as required?</td><td>The firm has manufactured three initial stability batches for the stability studies of Xiga-Met 5/850 Tablet with batch numbers i.e. XMA-T5-19, XMA-T6-19 and XMA-T7-19 and of Xiga-Met 5/1000 Tablet with batch numbers i.e. XMB-T5-19, XMB-T6-19 and XMB-T7-19. The accelerated studies were done in Climatic test chamber (Model: HPP-749; Making Memmert, Germany) and long-term studies were done in Climatic test chamber (Model: HPP-750, Making Memmert, Germany).</td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm had followed in-house SOP for fixing the batch size of stability batches.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td colspan="3">Xiga-Met 5/850 Tablets</td></tr>
<tr><td>XMA-T5-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMA-T6-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMA-T7-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td colspan="3">Xiga-Met 5/1000 Tablets</td></tr>
<tr><td>XMB-T5-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMB-T6-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMB-T7-19</td><td>2,000</td><td>03-2019</td></tr>
</table></td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm had protocols for testing of stability batches.</td></tr>
<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had developed method of Xiga-Met 5/850 Tablet (RD-PTM-16 C) and Xiga-Met 5/1000 Tablet (RD-PTM-17 C) and validated the test method (CCL-AMVR-220) for testing of stability batches.</td></tr>
</table>

<table>
<tr><td>27</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Dapagliflozin Propanediol Monohydrate and Metformin HCl API and the finished drug?</td><td>The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished product. However, the firm was advised to qualify the equipments / instruments from authorized bodies.</td></tr>
<tr><td>29</td><td>Do your method of analysis stability indicating?</td><td>The firm had conducted stress testing of finished product.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR Compliant?</td><td>API testing, FPP testing and compatibility testing had been conducted on HPLCs which were not 21 CFR compliant.
However, the firm has procured 21 CFR part 11 compliant HPLC.</td></tr>
<tr><td>31</td><td>Can you show Audit trail reports on Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 testing?</td><td>Initially, audit trail was not enabled. However, log of data was available on the HPLCs. The data was also checked through hard copies of chromatograms.
However, 6 months onwards stability studies were performed on audit trail active software.</td></tr>
<tr><td>32</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches kept on stability testing:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Tablets used for stability studies</th><th>Remaining Quantities of Stability Btaches</th></tr>
<tr><td colspan="4">Xiga-Met 5/850 Tablets</td></tr>
<tr><td>XMA-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMA-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMA-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td colspan="4">Xiga-Met 5/1000 Tablets</td></tr>
<tr><td>XMB-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMB-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMB-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr>
</table></td></tr>
<tr><td>33</td><td>Do you have stability batches kept on stability testing?</td><td>The firm had stability batches kept on stability testing.</td></tr>
<tr><td>34</td><td>Do you have valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablets production and analysis?</td><td>The firm had valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 production and analysis.</td></tr>
<tr><td>35</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Adequate monitoring and control was available for stability chamber. The firm was advised to improve alarm system.</td></tr>
<tr><td>36</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>Requisite facilities are satisfactory and GMP compliant (DRAP ref. no. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 valid for 3 years).</td></tr>
</table>

VERIFICATION:

(i) The firm selected M/s. Fuxin Long Rui Pharmaceutical Co. Ltd., China for Dapagliflozin Propanediol Monohydrate based on their vendor evaluation mechanism. Panel verified following documents regarding source:

- ADC attested invoice
- Trial cards

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. CCL Pharmaceuticals (Pvt.) Ltd., at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan have conducted stability studies of the following products. However few points are being recorded for the kind perusal of the Drug Registration Board, against questions 6, 19, 28, 30, 31 and 35 of the check list.

Decision: Registration Board decided to approve registration of "Xiga-Met 5/850 Tablet & Xiga-Met 5/1000 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

d. Exemption from onsite verification of stability data

2157.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.**
	Brand Name +Dosage Form + Strength	**Lina 5mg tablets**
	Composition	Each film coated tablet contains: Linagliptin ……5mg
	Diary No. Date of R& I & fee	Dy. No 1271 dated 28-11-2016, Rs.50,000/- 24-11-2016
	Pharmacological Group	Anti-diabetes
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Lina 5mg tablets
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China
API Lot No.	161031
Description of Pack (Container closure system)	Alu/Alu blister in unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH
Time Period	Accelerated: 6 months

	Real Time: 6 months		
Frequency	Accelerated: 0,1,2,3,4,5,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	LNA-PB-005002	LNA-PB-005003	LNA-PB-005004
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	December 2017	December 2017	December 2017
Date of Initiation	December 2017	December 2017	December 2017
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	• Copy of COA for Linagliptin (Batch# 161031) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
161031	HK1701121-B	80gm	20-03-2017

All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Lina tablets 5mg and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 09-05-2019 (R&I no. 5661)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: i. The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA

<table>
<tr><td></td><td></td><td>ii. The firm has audit trail Reports on testing.
iii. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th><th>Date of approval by DRAP</th></tr>
<tr><td>161031</td><td>HK1701121-B</td><td>80gm</td><td>20-03-2017</td></tr>
</table></td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No document has been submitted to establish the procurement of reference standard and impurity standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted document of “Rationale for Selection of manufacturer of API ‘Linagliptin’”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>The firm has submitted certificate of analysis for API, working standard & impurity standards.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in Research & product development & scientific Development and Analytical services comprising of 19 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted authorized photocopy of Product Development Protocol & Stability protocols for applied product.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Lina 5mg tablet such as.
<table>
<tr><th colspan="3">Lina 5 mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>LNA-PB-005002</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005003</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005004</td><td>12-2017</td><td>2000 Tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning details of the remaining quantities of tablets kept at accelerated and real time stability studies.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical charts for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
</table>

<table>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Linagliptin.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Specification/Testing Method of Finished Product for Lina 5mg tablets along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc. for applied formulation.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Linagliptin</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Lina 5mg tablet.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has stated that they have similar qualitative formulation as that of the innovator product.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted results for comparative dissolution results in 0.1N HCl buffer against the reference product “Tradjenta tablets 5mg”.
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Jenner</th></tr>
<tr><td>Brand name</td><td>Tradjenta tablets 5mg</td><td>Lina 5mg tablet</td></tr>
<tr><td>Batch No.</td><td>655575</td><td>LNA-PB-005002</td></tr>
</table>
• Firm has submitted f2 factor value for each time point.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted method audit trail reports of stability studies of applied formulations.</td></tr>
</table>

Remarks of Evaluator:

Sr. #	Observations	Response of Firm
1	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) as written in finished product specifications	The analysis is performed for sample solutions and standard solutions in dissolution is 0.005mg/ml as already mentioned in whole stability studies testing records. In finished product specifications, by typing mistake, 2ml is written instead of 1 ml which lead to read as 0.01mg/ml instead of 0.005mg/ml. (It is just typing mistake and is rectified)
2	Retention time of 1st Month stability studies is about 5 mints whereas on all other time points is about 3 mints	Retention time at whole stability studies is about 3 mints instead of 1st Month time point analysis, which is about 5 minutes. **Remarks:** The pressure of HPLC column was increased at 1st Month analysis time point due to which retention time for both sample and standard solution was increased to about 5 minutes from 3 minutes. After that we rectified it and separate column is specified for whole stability studies of said product. Further, more analytical method validation is performed and retention time during AMV was also about 3 minutes.
3	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) in dissolution at 1st month time point analysis	As earlier discussed in point 3, In finished product specifications, by typing mistake, 2ml is written instead of 1 ml.

		The problem was rectified and analysis at all time points were performed at 0.005mg/ml concentration after this time point.

Decision of 296th meeting: Registration Board decided to approve registration of "Lina 5mg tablets (Linagliptin)" by M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration letters shall be issued after decision on comments of IPO regarding patent matter for the applied formulation.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2158	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43103 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA			
Drug	Jarzin-Met 5/850mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/19030439		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	May 2019	May 2019	May 2019
Date of Initiation	May 2019	May 2019	May 2019
Batch Nos.	**19PD-109**	**19PD-119**	**19PD-120**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd.

	(Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2159	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/500mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43106 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA

Drug	Jarzin-Met 12.5/500mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/18102071
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton

Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months			
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)			
Manufacturing date	Feb 2019		Mar 2019	Mar 2019
Date of Initiation	Mar 2019		Mar 2019	Mar 2019
Batch Nos.	**19PD-039**		**19PD-065**	**19PD-067**
Batch Size	1,500 Tablets		1,500 Tablets	1,500 Tablets
No. of Batches	03			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2160	M/s The Searle Company Limited	Jarzin-Met 12.5/1000mg Tablets	Form-5D Dy. No: 43104 Dated. 18-Dec-2018	SYNJARDY TABLETS Approved by USFDA

	F-319 S.I.T.E. Karachi, Pakistan.	Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 1000mg Anti-Diabetes Mfg. Specs.	Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	

STABILITY STUDY DATA			
Drug	Jarzin-Met 12.5/1000mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19010053		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	03 2019	04 2019	04 2019
Date of Initiation	04 2019	05 2019	05 2019
Batch Nos.	**19PD-087**	**19PD-100**	**19PD-102**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg

			Empagliflozin: Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg	
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.			Yes	
Commitment to continue real time stability study till assigned shelf life of the product.			Yes	
Commitment to follow Drug Specification Rules, 1978.			Yes	
Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2161	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43105 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA
STABILITY STUDY DATA				
Drug		Jarzin-Met 12.5/850mg Tablets		
Name of Manufacturer		M/s The Searle Company Limited.		
Manufacturer of API		**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.		**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19030439		
Description of Pack (Container closure system)		Alu-Alu Blister in unit carton		
Stability Storage Condition		**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency		**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date		04 2019	04 2019	May 2019
Date of Initiation		May 2019	May 2019	May 2019
Batch Nos.		**19PD-105**	**19PD-106**	**19PD-108**
Batch Size		2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)				
DOCUMENTS TO BE PROVIDED			**STATUS**	
COA of API			Yes	
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.			**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023.	

	Empagliflozin: Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.

1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
4.	Stability study data of API from API manufacturer	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of

	by concerned regulatory authority of country of origin.	M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
7.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
11.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator^{II}:		

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**	**Evaluated by**

2162	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/500mg Tablets Each film-coated tablet contains: Empagliflozin …… 5mg Metformin HCl …… 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43095 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS	AD PEC-II

STABILITY STUDY DATA			
Drug	Jarzin-Met 5/500mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl:** M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India		
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin HCl**: MEF/17091410		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Apr 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-086**	**18PD-099**	**18PD-090**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg)

	Empagliflozin: Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Previous Remarks of Evaluator:

- Salt from of Metformin is not mentioned in Form 5-D.
- Firm has submitted that "the material Empagliflozin" having batch no. D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.
- Content uniformity test has not been performed for Empagliflozin to determine uniformity of dosage unit.
- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2163	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/1000mg Tablets Each film-coated tablet contains: Empagliflozin…….5mg Metformin HCl …….1000mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43102 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS

STABILITY STUDY DATA

Drug	Jarzin-Met 5/1000mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.
Manufacturer of API	**Empagliflozin**: Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin**: MEF/17091410
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton

Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Mar 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-084**	**18PD-087**	**18PD-098**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator:

- Salt form of Metformin is not mentioned in Form 5-D.
- The acceptance criteria of dissolution test submitted by firm for applied formulation is NLT 75% (Q) after 30 minutes for both Metformin HCl & Empagliflozin. While the dissolution specification of the innovator product i.e., "Synjardy", revealed in Clinical Pharmacology & Biophartmaceutics review by USFDA (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206111Orig1s000ClinPharmR.pdf) declares the dissolution specification for 20 minutes for all strengths of both drug substances i.e., Metformin HCl & Empagliflozin.
- Firm has submitted that "the material Empagliflozin" having batch no D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.

- Upon communication of above observation the firm has referred to following definition of "re-test period", from Annex 2 (Stability testing of active pharmaceutical ingredients and finished pharmaceutical products) of WHO Technical Report Series, No. 953, 2009:

re-test period
"The period of time during which the API is expected to remain within its specification and, therefore, can be used in the manufacture of a given FPP, provided that the API has been stored under the defined conditions. After this period a batch of API destined for use in the manufacture of an FPP should be re-tested for compliance with the specification and then used immediately. **A batch of API can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification.** For most substances known to be labile, it is more appropriate to establish a shelf-life than a re-test period. The same may be true for certain antibiotics."

- Moreover, firm has submitted that they have not performed "Residual solvents testing" & "Chiral impurity testing" at the time of re-test since both these are process related impurities and if they are within specification than there is no need to further analyze at stability & at re-test.

- It is pertinent to mention that as per applicable guidelines, the API could be used immediately (within one month) after the retest, but one time retest analysis could not be used to extend the shelf life of the API in term of retest date.

- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Decision of 293rd meeting: Registration Board deferred the cases for following reasons:

- Clarification/Justification shall be submitted by the firm for extending shelf life of the API for 1 year on the basis of one-time retest.
- Stability studies of Empagliflozin API from the API manufacturer.
- Submission of revised Form 5 with correct composition, declaring the salt form of Metformin.

Firm's response:

- Firm has referred to their SOP of "Retesting of Raw materials".
- For Empagliflozin firm has submitted both accelerated stability studies (6 months) & long-term stability studies report (36 months) of three batches from the API manufacturer.
- Revised Form 5 D with correct composition, declaring the salt form of Metformin as "Metformin HCl" has been submitted.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet and provided the following documents in conjunction with the checklist approved by the Registration Board.

1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.

4.	Stability study data of API from API manufacturer	**Metformin HCl:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches. **Empagliflozin:** Firm has submitted both stability studies & long term stability studies reports of three batches
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
7.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
11.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies for 5/1000mg tablet in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator^{II}:		
Decision: Registration Board decided to approve registration of "Jarzin-Met 5/1000mg Tablets, Jarzin-Met 5/500mg Tablets, Jarzin-Met 12.5/850mg Tablets, Jarzin-Met 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets and Jarzin-Met 5/850mg Tablets by M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan. Manufacturer will place first three commercial batches of all 6 products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

2164.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 800mg Tablets

	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..800mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

2165.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 200mg Tablets
	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..200mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Esli Tablet	
Name of Manufacturer	"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."	
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India	
API Lot No.	Eslicarbazepine acetate: 17EA00012	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Esli 200mg tablet	Esli 800mg tablet
Batch#	ESL-289310-3, ESL-289210-2, ESL-289010-1	ESL-290311-7, ESL-290211-6, ESL-290111-5
Batch Size	1554 Tablets	421 Tablets

Manufacturing Date	Oct-2018	Nov-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Provided
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate # 19061470) issued to M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Batch No.	**Invoice No.**	**Quantity Imported.**
17EA00012	EL/2021700092	2Kg

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Esli 200mg & 800mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted.

<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th></tr><tr><td>17EA00012</td><td>EL/2021700092</td><td>2Kg</td></tr></table></td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted a non-commercial invoice from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India for the import of 1000mg of working standard</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• The firm has provided copy of GMP ceretificate (Certificate # 19061470) issued to M/s M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Hubeii Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure”,
SOP No: PDV-FM-068 with effective date 02-03-2018.
Version no: 01
• Copy of “Vendor’s Audit form” filled for M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• The firm has submitted certificate of analysis for API (Batch# 17EA00012), working standard (Batch#WS/EA/03) for Eslicarbazepine acetate.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 17 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted photocopy of Development Protocol `for Lab scale batch manufacturing of Esli 200mg & 800mg Film coated tablets.<br>• Project code # HPL/10/18/ESL<br>• Issued on Oct, 2018<br>• The SOP mentions` the details of master formulation & manufacturing method for both products. Copies of stability protocols have also been submitted for both products.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Vonopran tablets, such as.

<table><tr><th colspan="3">Esli 200mg Tablet</th></tr><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>ESL-289010-1</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><td>ESL-289210-2</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><td>ESL-289310-3</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><th colspan="3">Esli 800mg Tablet</th></tr><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>ESL-290111-5</td><td>Nov-2018</td><td>421 Tablets</td></tr><tr><td>ESL-290211-6</td><td>Nov-2018</td><td>421 Tablets</td></tr><tr><td>ESL-290311-7</td><td>Nov-2018</td><td>421 Tablets</td></tr></table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet for all trial batches of both Esli 200mg & 800mg tablets.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Eslicarbazepine acetate
• Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs have been submitted.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for Esli 200mg tablets & Esli 800mg tablet along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Eslicarbazepine acetate from API manufacturer for both Accelerated (40°C ± 2°C / 75% ± 5%RH) 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 48 months only.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Esli tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet and also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted F2 factor protocol & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Esli 200mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 200mg tablet</td><td>Esli 200mg tablet</td></tr>
<tr><td>Batch No.</td><td>ZBCB</td><td>ESL-289210-2</td></tr>
<tr><th colspan="3">Esli 800mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 800mg tablet</td><td>Esli 800mg tablet</td></tr>
<tr><td>Batch No.</td><td>PXFZ</td><td>ESL-290111-5</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
a. pH 1.2 HCl buffer
b. pH 4.5 Acetate buffer
c. pH 6.8 Phosphate buffer
• As per submitted reports both reference and trial product are comparable as with acceptable f2 value.
• Firm has submitted UV spectrums and raw data sheets for the CDP study.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
</table>

Remarks of Evaluator[II]:
Decision: Registration Board decided to approve registration of "Esli 800mg Tablets (Eslicarbazepine Acetate) and Esli 200mg Tablets (Eslicarbazepine Acetate) M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

2166.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 90mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…….90mg"
	Diary No. Date of R& I & fee	Dy. No 1243 dated 10-01-2019, Rs.20,000/- Dated 10-01-2019
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance
	Remarks of the Evaluator[II]	

2167.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 60mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor……60mg"
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013, Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Tri-Plat Tablets 60mg
Name of Manufacturer	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1, SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India.
API Lot No.	8281034.
Description of Pack (Container closure system)	Alu-Alu blister in unit carton

Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Trip-Lat 60mg	Trip-Lat 90mg
Batch#	Trial#01, Trial#02, Trial#03	Trial#01, Trial#02, Trial#03
Batch Size	1500 Tablets	1500 Tablets
Manufacturing Date	05-2019	06-2019

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Trip-Lat 60mg & 90mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.

1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Saferon tablets (Sofosbuvir 400 mg)", which was presented in 278th meeting of Registration Board held on 29-31st Jan, 2018 **Observations:** Panel has observed that firm has improved as follows: • Floor has been renovated and painted with epoxy paint (anti-bacterial). • Old windows were replaced with double glazed windows. • Special Aluminium fixtures with rounded edges were installed. • Upgraded HVAC with pressure differentials was provided. • Firm has 06 tablet compression machines with capability of producing double layered tablets. Keeping in view improvements made by the firm as identified in the previous inspection, panel recommends the facilities of the firm for manufacturing of Saferon (Sofosbuvir 400mg) tablets and give rating of very Good. **Decision:** Registration Board decided to approve registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
3.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
4.	Stability study data of API from API manufacturer	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 19011176) for M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1,SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India issued by Food & Drug Control Administration, Gujarat State, valid upto 08-08-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted following. •Commercial invoice attested by AD (I&E) DRAP, Islamabad dated 22-10-2018, Islamabad confirming import of Ticagrelor

<table>
<tr><td></td><td></td><td>(1.125Kg), Batch# 8281034.</td></tr>
<tr><td>7.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Firm has submitted authorized protocols for the development of Trip-Lat Tablets.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the three batches.
<table>
<tr><th colspan="3">Tri-Plat 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><th colspan="3">Tri-Plat 90mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>06-2019</td><td>1500 Tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Brilinta tablet for both strengths concluding f2 value within acceptable limit.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for HPLC analysis for all the three batches of Trip-Lat 60mg & 90mg tablets</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator[II]:
• Submitted batch manufacturing record declare use of 3% overage of API.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Tri-Plat Tablets 60mg (Ticagrelor) and Tri-Plat Tablets 90mg (Ticagrelor) by M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IV-A conditions.</td></tr>
</table>

Case no. 07 Applications on Form 5F

2168.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28339: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…60mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
API Lot No.	RD-TG- 201810081
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision:

1.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.

	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28340: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
API Lot No.	RD-TG- 201810081
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Observation	Firm's response
Justify the dissolution specification NLT 80%(Q) after 45 minutes, since the	• As per USFDA guidelines *"dissolution testing of Immediate release solid oral*

USFDA chemistry review document of the innovator product specify dissolution testing at two points i.e. NLT (Q) at 45 minutes and NLT (Q) at 60 minutes. • USFDA guidelines "dissolution testing of Immediate release solid oral dosage form" recommends that for slowly dissolving or poorly water soluble drugs, a two point dissolution specification, one at earlier time to include a dissolution range (a dissolution window) and the other at a later point (30, 45 or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product. The innovator product has also used the same approach and selected two time points for dissolution, justify how your finished product specification without a test for measure of dissolution range at 45 minutes & at 60 minutes to ensure 85% drug release be considered similar to that if innovator product. If your product shows more than 85% release in 45 minutes, how it can be considered similar with innovator product in terms of drug release	*dosage form"* Two time point dissolution analysis is recommended for development studies of BCS class II drugs and after development the final dissolution specifications will be set while the Ticagrelor falls in BCS class IV and many pharmacopeal monograph of BCS class IV and II available in pharmacopeia having only one time interval for dissolution test i.e. Clarithromycin , Leflunomide - • Furthermore, According to FDA chemistry review, the agency recommend the applicant (Innovator) to submit a supplement to set the final acceptance criteria for dissolution testing. • It is also mentioned in FDA reviews of Innovator data that the product shows consistent results at 45 minutes and the agency recommend to revised the proposed dissolution • To ensure the release pattern of SAMI product same as Innovator product, Comparative dissolution against innovator at different time point (i-e 45 and 60 minutes) has been performed and both products achieve the dissolution more than 80%(Q) after 45 minutes.**)** • We have also done testing at both time intervals i.e. 45 & 60 minutes at 9th month stability study at long term on stability batches • On the basis of above we have set the specification for dissolution i-e NLT 80% (Q) at 45 minutes.

Decision: Registration Board deferred the applications of Taglor 60mg Tablet & Taglor 90mg tablet and directed the firm to submit dissolution testing data with time pints of 45 minutes & 60 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

2169.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"**
	Name, address of Manufacturing site.	"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2207: 21-02-2020
	Details of fee submitted	PKR 20,000/-: 18-02-2020
	The proposed proprietary name / brand name	**D-3 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each ml Contains: Cholecalciferol…….5mg"
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Vitamin D (A11CC05)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1ml x 1's, 1ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by ANSM of France
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharmaceuticals (Reg.#063450)
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 28-11-2019.
	Name and address of API manufacturer.	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Product:	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Pharmaceutical Equivalence	Firm has submitted comparison analysis studies against the reference product of Bouchara Recordati France.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data for the assay test performed by UV spectrophotometer.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
API Lot No.	CLC0419019
Description of Pack (Container closure system)	1 ml clear glass ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml
Batch Size	10000 Ampoules	10000 Ampoules	10000 Ampoules
Manufacturing Date	06-2019	06-2019	06-2019

Sr.#	Data required	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Canzin tablets", which was conducted on 14-03-2019, and was presented in 289th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail on testing reports is available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (No. 181529) issued by the Jiangsu Drug Administration in the name of M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India has been submitted which was valid upto 02-01-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. RV1002100166) attested by AD DRAP Karachi dated 09-04-2019, for import of 0.2Kg of Cholecalciferol (batch# CLC0419019)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator^{II}:

- Firm has used 15% overage in the master formulation and submitted following justification for it:
  "Vitamin D3 is a heat sensitive material, when used as an active ingredient, cannot be terminally sterilized therefore subjected to filtration through microbial retentive materials. It is aseptically filled and sterilized by filtration by using 0.2um filter which have high chances of clogging and absorption. The assay limit is therefore set at 95% - 105% at the time of release, as API is lost during filtration process. Hence, 15% overage is used to compensate the process loss."
  Whereas, our result in accelerated stability are within the limit which justify the assay limit of 90% - 110% for shelf life. However, we undertake that we will revise our limit with 90% to 115% in finished product specification."
- Firm has applied UV method for the Assay analysis of drug product during stability studies.

Decision: Deferred for justification of performing Assay analysis of the drug product by UV spectrophotometric method.

2170.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"**
	Name, address of Manufacturing site.	"M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No28011: 23-12-2019
	Details of fee submitted	PKR 50,000/-: 23-12-2019
	The proposed proprietary name / brand name	**Etoxib tablet 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each film coated tablet contains: Etoricoxib …… 30mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	COX-2 inhibitor
	Reference to Finished product specifications	Manufacturer specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	Rs. 200/tablet
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	M/S Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India.
API Lot No.	84170527
Description of Pack	Alu-Alu blister in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	TF-051118	TF-061118	TF-071118
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	11-2018	11-2018	11-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by the FDA Maharashtra India in the name of M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, - Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India has been submitted which is valid upto 24-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
84170527	F2000002386	100Kg	01-03-2018

REMARKS OF EVALUATOR[II]:

Observation	Firm's response
Justification of 5% overage in the formulation(s) of stability batches shall be submitted since Overages are not acceptable unless fully justified.	This addition was not due to any specific reason, however we have reviewed the stability data of these three trial batches and noted that Assay & Dissolution results remain well within limits without significant change after 6 months accelerated stability.

	Furthermore we have evaluated that 5% overage impact on assay & Dissolution results and if we subtract 5% overage impact on assay & dissolution values, our values are still within limits. Furthermore we hereby commit that in commercial batch formulation of Etoxib tablet 30mg, overage will not be included.

Decision: Registration Board decided to approve registration of "Etoxib tablet 30mg (Etoricoxib) by M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

2171.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals, S-95, SITE, Karachi.**
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23129: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 2.5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 2.5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg	

	tablet and the results are within acceptable limit of f2 value.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20180205Y		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

2172.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23128: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s, 20’s, 30’s
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Remarks of Evaluator: • Stability studies of drug substance as per Zone IVa conditions have been submitted.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile

		studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20180205Y		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Decision: Registration Board decided to approve registration of "Xaby 2.5mg tablet (Apixaban) and Xaby 5mg tablet (Apixaban) by M/s Sami Pharmaceuticals, S-95, SITE, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

Item No. -: Agenda of Evaluator PEC-VIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. New cases

2173.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …120mg"
	Diary No. Date of R& I & fee	Dy.No 9382 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	----
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	Applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2174.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …60mg"
	Diary No. Date of R& I & fee	Dy.No 9380 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Starcox 60 mg tab by Getz Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.

	Remarks of the Evaluator [VIII]	
	Decision: Approved as per innovator's specification.	
2175.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox 500mg Tablets
	Composition	"Each dispersible contains: Deferasirox…500mg"
	Diary No. Date of R& I & fee	Dy.No 9378 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 500mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved as per innovator's specification.	
2176.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox250mg Tablets
	Composition	"Each dispersible contains: Deferasirox…250mg"
	Diary No. Date of R& I & fee	Dy.No 9379 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2177.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 100mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…100mg"
	Diary No. Date of R& I & fee	Dy.No 9374 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 100mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2178.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 200mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…200mg"
	Diary No. Date of R& I & fee	Dy.No 9375 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 200mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2179.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 1000mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…1000mg"
	Diary No. Date of R& I & fee	Dy.No 9362 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicia 1000mg Tablet of Martin Dow
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2180.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma.

		Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 750mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…750mg"
	Diary No. Date of R& I & fee	Dy.No 9361 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Vetrawin Tablets 750mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2181.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 500mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…500mg"
	Diary No. Date of R& I & fee	Dy.No 9360 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Vetrawin Tablets 500mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2182.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Danon Tablets 4mg
	Composition	"Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…4mg"
	Diary No. Date of R& I & fee	Dy.No 9376 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA

	Me-too status	Zofran tablet 4mg of Glaxo welcome
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2183.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Serna Tablets 100mg
	Composition	"Each Film Coated Tablet Contains: Sertraline (as hydrochloride)…100mg"
	Diary No. Date of R& I & fee	Dy.No 9370 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	SSRIs
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Saytral 100mg Tablets of Sayyed Pharmaceuticals
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2184.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Grezon 90mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Diary No. Date of R& I & fee	Dy.No 9986 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2185.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"

	Brand Name +Dosage Form + Strength	Clozon 145mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…145mcg"
	Diary No. Date of R& I & fee	Dy.No 9978 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2186.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 72mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…72mcg"
	Diary No. Date of R& I & fee	Dy.No 9977 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	

2187.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 290mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…290mcg"
	Diary No. Date of R& I & fee	Dy.No 9979 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2188.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Luzon 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lurasidone (ashydrochloride)…40mg"
	Diary No. Date of R& I & fee	Dy.No 9980 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(uncoated)Latuda (ema film)
	Me-too status	-----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Reference Product is approved as uncoated tablet which is different from applied formulation submit either composition & master formulation after correction alongwith submission of requisite fee or evidence of reference product approved as film coated tablet.

	Decision: Deferred for the following: • **Submit either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **Submit either composition & master formulation after correction along with submission of requisite fee as reference product is approved as uncoated tablet or otherwise evidence of reference product approved as film coated tablet.**	
2189.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 12.5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9972 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (JARDIAMET 12.5 mg/850 mg)
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2190.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9973 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA JARDIAMET 5 mg/850 mg
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.

	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2191.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Linazin Tablet 25/5mg
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No. 9969 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	7's,14's,28's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Glyxambi25 mg/5 mg tablets)
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.
	Decision: Deferred for the following: • **Submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **For opinion of Legal Affairs Division regarding linagliptin for its patent rights.**	
2192.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Bimzin Eye Dop 0.3mg/ml
	Composition	"Each ml contains: Bimatoprost…0.3mg"
	Diary No. Date of R& I & fee	Dy.No 9966 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-glaucoma
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	15ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (solution) (LUMIGAN: 0.03% **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Lumigan eye Drops of Barret Hodgson
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	

2193.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Detozin Injection 2ml
	Composition	"Each 2ml ampoule contains: Dexketoprofentrometamol 73.80mgeq to Dexketoprofen…50mg"
	Diary No. Date of R& I & fee	Dy.No 9967 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	5's,10's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.
	Decision: deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
2194.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	TimprostOpthalmic Solution 50mcg/5mg
	Composition	"Each ml contains: Latanoprost…50mcg Timolol(as maleate)…5mg"
	Diary No. Date of R& I & fee	Dy.No 9976 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Prostaglandin analogue, antiglaucoma drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	2.5ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (solution)
	Me-too status	Latlol eye drops of Genix

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2195.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Dilatic Tablet 500mcg
	Composition	"Each Film Coated Tablet Contains: Roflumilast…500mcg"
	Diary No. Date of R& I & fee	Dy.No 10673 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Phosphodiesterase-4 (PDE-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30,s:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2196.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nepawal 1mg/1ml Opthalmic Solution
	Composition	"Each ml of opthalmic suspension contains: Nepafenac…1mg"
	Diary No. Date of R& I & fee	Dy.No 10672 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	3ml, 5ml(LDPE bottle):As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(suspension)
	Me-too status	Venac 0.1% of Vega Pharma
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2197.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Artazon3ml Injection
	Composition	"Each ml contains: Atracurium besilate…10mg"

	Diary No. Date of R& I & fee	Dy.No 10615 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Nondepolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's,10's :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicurium injection 10mg/ml of Elite Pharma (2.5ml)
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	*MHRA 2.5 ml: Type I glass ampoule in packs of 5 ampoules. 5 ml: Type I glass ampoule in packs of 5 ampoules. 25 ml: Type I glass vial with rubber stopper in packs of 1 vial. • Evidence of approval of applied formulation in applied volume i.e. 3ml in reference agencies. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Submit Me Too in applied volume.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting in applied volume i.e 3ml.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in applied volume i.e 3ml..**	
2198.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nevazon 5/80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…5mg Valsartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 10674 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	beta blocker/ angiotensin receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	-----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2199.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma.

		Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 50mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…50mg"
	Diary No. Date of R& I & fee	Dy.No 9373 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 50mg Tablet of Genix Pharma
	GMP status	Dated: 26-04-2019 GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator VIII	
	Decision: Approved.	
2200.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Nitaxid 100mg/5ml Dry Suspension
	Composition	"Each 5ml Suspension after Reconstitution Contains: Nitazoxanide…100mg"
	Diary No. Date of R&I & fee	Dy.No 40911 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	30ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Nitox 100mg /5ml of M/s Regal Pharmaceuticals,
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2201.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Diclowin 50mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg" (core, enteric coating)
	Diary No. Date of R&I & fee	Dy.No 40927 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications

	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Dicmaf 50mg Tablet of Mafins
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 5. General Tablet Section 6. General Capsule Section 7. Oral Dry Powder Suspension Section(General) 8. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2202.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Serat 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline as hydrochloride…50mg"
	Diary No. Date of R&I & fee	Dy.No 40932 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Saytral 50mg Tablets of Sayyed Pharmaceuticals
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 9. General Tablet Section 10. General Capsule Section 11. Oral Dry Powder Suspension Section(General) 12. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2203.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Eprijen 50mg Tablet
	Composition	"Each sugar coated tablet contains: Eperisone HCL…50mg"
	Diary No. Date of R& I & fee	Dy.No 39902 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	30's, As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in PMDA
	Me-too status	Feloni 50mg Tablet of Hirani Pharmaceutical,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2204.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Rolajen 500mg XR Tablets
	Composition	"Each extended release tablet contains: Ranolazine …500mg"
	Diary No. Date of R& I & fee	Dy.No 40848 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	cardiac preparations
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)TGA
	Me-too status	Ranagin XR 500mg of Hilton Pharma
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit manufacturing method for relevant formulation as submitted method is of film coated tablet.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product.	
2205.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	"Jenfine Tablets 125mg
	Composition	"Each Tablet Contains: Terbinafine(as HCL)…125mg
	Diary No. Date of R& I & fee	Dy.No 39905 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Antifunga
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA& TGA
	Me-too status	Logirid Tablet 125mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision:Approved.	
2206.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Setrom 8mg Tablets

	Composition	"Each Film Coated Tablet Contains: Ondansetron dihydrate eq to Ondansetron …8mg"
	Diary No. Date of R& I & fee	Dy.No 40296 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Zofran Tablets 8mg of Glaxo Wellcome Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
2207.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Histajen 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ebastine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40843 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Desid Tablets 10mg ofGillman Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
2208.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jen-Heim Tablet
	Composition	"Each chewable tablet contains: Iron III Hydroxide polymaltose complex eq to elemental iron…100mg Folic Acid…0.35mg"
	Diary No. Date of R& I & fee	Dy.No 40852 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	RBC-F tablets by Genix
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.

	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2209.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenprox SR Tablets 12.5mg
	Composition	"Each SR Tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 39906 dated 04-12-2018 Rs.20,000/
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Panox CR Tablet 12.5 mg of M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant & in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 12.5 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2210.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jentadin Tablets 5mg
	Composition	"Each Film Coated Tablet Contains: Desloratadine…5mg"
	Diary No. Date of R& I & fee	Dy.No 39907 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	ANTIHISTAMINES
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2211.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Piracet 800mg Tablets

	Composition	"Each Film Coated Tablet Contains: Piracetam…800mg"
	Diary No. Date of R& I & fee	Dy.No 39901 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Troopil Tablets 800 mg of ParamountPharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2212.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Hiace5mg Tablet
	Composition	"Each uncoated tablet contains: Ramipril…5mg"
	Diary No. Date of R& I & fee	Dy.No 41393 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Ramy 5mg Tablet of Getz Pharma Karachi
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved with USP specifications	
2213.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Diora 50mg Capsule
	Composition	"Each Capsule Contains: Diacerin…50mg"
	Diary No. Date of R& I & fee	Dy.No 41392 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-osteoarthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Dorsett 50mg Capsule of Weather Folds Pharmaceuticals,
	GMP status	Dated: 23-02-2018 & 26-02-2018

		Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2214.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Renavel 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sevelamer as HCL…400mg"
	Diary No. Date of R& I & fee	Dy.No 41391 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Foseal-800 Tablets Of M/S. Sncura Enterprises
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	Reference product is "Each Film Coated Tablet Contains: Sevelamer HCL…400mg"
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **"Each Film Coated Tablet Contains:** **Sevelamer HCL…400mg"**	
2215.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Cande 16mg Tablet
	Composition	"Each uncoated tablet contains: Candesartan Cilexetil …16mg"
	Diary No. Date of R& I & fee	Dy.No 41408 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Miscand 16mg Tablet of Mission Pharma.
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm

		M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	On fee challan strength of tablet is 160 instead of 16.
	Decision: Approved as applied formulation is not available in strength of 160mg.	
2216.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Doxy Tablets 400mg
	Composition	"Each Film Coated Tablet Contains: Doxofylline…400mg"
	Diary No. Date of R& I & fee	Dy.No 40291 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant.
	Decision: Deferred for submission of manufacturing method for relevant formulation in line with reference product.	
2217.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Ferriject 500mg/10ml Injection
	Composition	Each 10ml Ampoule Contains: Iron as ferric carboxymaltose…500mg
	Diary No. Date of R& I & fee	Dy.No 40162 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (vial)
	Me-too status	Ferinject Injectable.Each 10ml vial contains:- Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2218.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"

	Brand Name +Dosage Form + Strength	Isofer 1000mg Injection
	Composition	"Each 10 ml Ampoule Contains: Iron as Iron III Isomaltoside…1000mg"
	Diary No. Date of R& I & fee	Dy.No. 40158 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2219.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	C-Cox 200mg Capsule
	Composition	"Each Capsule Contains: Celecoxib…200mg"
	Diary No. Date of R& I & fee	Dy.No 41057 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Selxib -200mg Capsule OF M/s Fynk Pharmaceuticals,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2220.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Rotcam 20mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Piroxicam…20mg"
	Diary No. Date of R& I & fee	Dy.No 40178 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m route)
	Me-too status	Piroxinor 20mg Injection ofM/s Nortech Pharmaceuticals, Pvt. Ltd

	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2221.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden-Plus 75/20 mg Injection
	Composition	Each 2ml Ampoule Contains: Diclofenac Sodium…75mg Lidocaine Hydrochloride…20mg
	Diary No. Date of R& I & fee	Dy.No 40177 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID, Local anesthetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	2ml (10's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Swiss medic Diclofenac Mepha Injection by Mepha Pharm
	Me-too status	Lidoran of Danas Pharma
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2222.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden 75mg/3ml Injection
	Composition	"Each 3ml Ampoule Contains: Diclofenac Sodium…75mg"
	Diary No. Date of R& I & fee	Dy.No 40222 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m) but status is repealed.
	Me-too status	V-REN Liquid injection of M/s Regal Pharmaceuticals
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2223.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"

	Brand Name +Dosage Form + Strength	Megatron Plus Syrup
	Composition	Each 5ml Contains: Iron III Hydroxide polymaltose complex…50mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy.No 41132 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Heamatinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	60ml : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2224.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No 41738 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	14'sAs per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Barclor 250mg Tablet of Brand, Karachi .
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2225.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxflex Tablets 550mg
	Composition	Each film coated Tablet Contains: Naproxen Sodium…550mg
	Diary No. Date of R& I & fee	Dy.No 41727 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID

	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Freshnap Tablet 550mg of M/s Fresh Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2226.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxzole Tablets 500/400mg
	Composition	Each Tablet Contains: Diloxanide furoate…500mg Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy.No 41740 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-amoebic infection
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	15's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(as provide by firm) (not verifiable)
	Me-too status	Dizet DS Tablets of M/s Rasco Pharma
	GMP status	Dated: 26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Clarification regarding salt of metronidazole is required.
	Decision: Deferred for clarification regarding salt form of API "Metronidazole" in applied formulation.	
2227.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dicmax Tablets 50mg
	Composition	Each film coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 41728 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	innovator's Specifications

	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Pngo 50mg Tablet of M/s Innvotek Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2228.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 100mg
	Composition	Each Tablet Contains: Atenolol……..…100mg
	Diary No. Date of R& I & fee	Dy.No 41736 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	Me-too status	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2229.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 50mg
	Composition	Each Tablet Contains: Atenolol…50mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta bloker
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Atenocard Tablets 50mg of Fassgen Pharmaceuticals,

	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation; the firm the advice to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2230.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Famoday Tablet 20mg
	Composition	Each Film coated Tablet Contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Link-Live 20mg Tablet of Umema Pharma
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2231.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxtilium Tablets 10mg
	Composition	Each Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 41726 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Epodom 10mg Tablets of Atlantic Pharmaceutical
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2232.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fucimax Cream 2%/1%
	Composition	Each tube contains: Fusidic Acid…2% Hydrocortisone…1%
	Diary No. Date of R& I & fee	Dy.No 41733 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti- inflamatory
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	15gm: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (emc)
	Me-too status	Ucid-HC Cream of Ciba Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit label claim of applied formulation in line with reference. Clarification regarding salt form of Hydrocortisone is required. Evidence of section approval.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference.** • **Clarification regarding salt form of Hydrocortisone is required.** • **Evidence of required manufacturing facility i.e., Cream/ ointment section from licensing is required.**	
2233.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxsec Tablets
	Composition	Each Tablet Contains: Amlodipine besylate…5mg
	Diary No. Date of R& I & fee	Dy. No 41737 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator.	Reference product contains Amlodipine as besylate…5mg
	Decision: approved with USP specifications and in line with reference product with following composition: **"Each Tablet Contains:** **Amlodipine as besylate…5mg "**	
2234.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No 41739 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision:Approved.	
2235.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenmax Tablets 100mg
	Composition	Each film coated Tablet Contains: Diclofenac sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 41730 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed in film coating(enteric coated is available)
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2236.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 5mg Tablet
	Composition	"Each Tablet Contains: Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9094 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as "amlodipine as besylate 5mg tablet", submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition: **"Each Tablet Contains:** **Amlodipine as besylate…5mg "**	
2237.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 10mg Tablet
	Composition	"Each Tablet Contains: Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9095 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 10 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as amlodipine as besilate 10mg tablet, submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition:	

	"Each Tablet Contains: Amlodipine as besylate…10mg "	
2238.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9049 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 5/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet. Updated status of GMP from QA & LT Division.	
2239.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 10mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9048 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 10/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 10mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet. Updated status of GMP from QA & LT Division	

2240.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 9047 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	As per SRO
	Me-too status	Aldric-H 5/160/12.5mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 12.5mg in a tablet.** **Updated status of GMP from QA & LT Division**	
2241.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/10mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…10mg
	Diary No. Date of R&I & Fee	Dy.No 6334 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…10mg "**	
2242.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"

	Brand Name + Dosage Form + Strength	Amelopin Tablet 40mg/5mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…40mg Amlodipine besylate…5mg
	Diary No. Date of R&I & Fee	Dy.No 6333 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 40/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…40mg** **Amlodipine as besylate…5mg "**	
2243.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/5mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…5mg
	Diary No. Date of R&I & Fee	Dy.No 6335 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/5mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…5mg "**	
2244.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/5mg
	Composition	"Each Tablet Contains:

		Telmisartan…80mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9104 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating, submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2245.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9103 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product

		along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2246.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/10mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9105 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.MF contains ingredients of coating.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2247.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/10mg
	Composition	"Each Tablet Contains: Telmisartan…80mg

		Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9106 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2248.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 5/40mg Tablets
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9063 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product

		along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2249.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 10/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 9062 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 10mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2250.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 5/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9064 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2251.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 8125 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2252.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 10mg/40mg Tablet
	Composition	Each film coatedTablet Contains: Amlodipine as besylate…10mg Telmisartan…40mg

	Diary No. Date of R&I & Fee	Dy.No 8124 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2253.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/80mg Tablet
	Composition	Each film coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 8126 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 5/80 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2254.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8173 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's: Rs.600/-, Rs.840/-, Rs.1200/-, Rs.1680/-, Rs.1800/-, Rs.3600/-, As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2255.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8172 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2256.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8175 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2257.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/10mg
	Composition	Each tablet contains Telmisartan…40mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8174 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2258.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Diary No. Date of R&I & Fee	Dy.No.5953 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Fenaso 10mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2259.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5952 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA

	Me-too status	Fenaso 5mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2260.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 2mg
	Composition	Each film coated tablet contains: Risperidone…2mg
	Diary No. Date of R&I & Fee	Dy.No 8182 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 2mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2261.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 4mg
	Composition	Each film coated tablet contains: Risperidone…4mg
	Diary No. Date of R&I & Fee	Dy.No 8183 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 4mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2262.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 10mg
	Composition	Each film coated tablet contains: Rivaroxaban…10mg
	Diary No. Date of R&I & Fee	Dy.No 5957 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Xarelto 10 mg Tabs by Bayer

	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2263.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 15mg
	Composition	Each film coated tablet contains: Rivaroxaban…15mg
	Diary No. Date of R&I & Fee	Dy.No 5958 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited,C/21, S.I.T.E.,Karachi."
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2264.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 20mg
	Composition	Each film coated tablet contains: Rivaroxaban…20mg
	Diary No. Date of R&I & Fee	Dy.No 5959 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Rivox Tablet 20 mg of CSH, Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Mention isomeric form of rivaroxaban.(Innovator: S enantiomer)
	Decision: Approved with innovator's specifications.	
2265.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 5mg
	Composition	Each uncoated tablet contains: Aripiprazole…5mg
	Diary No. Date of R&I & Fee	Dy.No 5954 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Ariza 5mg Tablet of Hilton Pharma (Pvt.) Limited Karachi

	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2266.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 10mg
	Composition	Each uncoated tablet contains: Aripiprazole…10mg
	Diary No. Date of R&I & Fee	Dy.No 5955 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 10mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2267.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 15mg
	Composition	Each uncoated tablet contains: Aripiprazole…15mg
	Diary No. Date of R&I & Fee	Dy.No 5956 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 15mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2268.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 6.25mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R&I & Fee	Dy.No 6781 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker

	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Hidilol 6.25mg Tablets of Helix Pharma (Pvt.) Ltd; Karachi.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2269.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 12.5mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 6782 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 12.5mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2270.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…25mg
	Diary No. Date of R&I & Fee	Dy.No 6783 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 25mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2271.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Syrup 100mg/5ml(liq)
	Composition	Each 5ml of syrup contains: Doxofylline…100mg
	Diary No. Date of R&I & Fee	Dy.No 5944 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO

	Approval status of product in reference regulatory authorities	Doxofillina ABC 200 mg / 10 ml Syrup by M/s ABC Farmaceutici SpA –Corso Vittorio (Italian Medicine Agency (AIFA) Italy Approved)
	Me-too status	Profylline Syrup 100mg/ 5mlof Kaizen Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2272.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 500mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…500mg
	Diary No. Date of R&I & Fee	Dy.No 5947 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Ursochol 500 mg capsule, hard By Orifarm Generics A/S (Sweden Approved).
	Me-too status	Triptor Capsule 500mg of M/s CCL Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2273.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 250mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 5946 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Triptor Capsule 250mg of M/s CCL Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2274.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 16mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…16mg
	Diary No. Date of R&I & Fee	Dy.No 5951 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)

	Me-too status	Betoxen 16mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2275.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 8mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…8mg
	Diary No. Date of R&I & Fee	Dy.No 5950 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	3*10's: As per SRo
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)
	Me-too status	Betoxen 8mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2276.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name + Dosage Form + Strength	Barlev Injection 500mg/5ml
	Composition	Each 5ml contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Eplipsa 500mg/5ml Injection of Helix Karachi .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Reference Product:*KEPPRA injection contains 100 mg of levetiracetam per mL. It is supplied in single-use 5 mL vials containing 500mg levetiracetam, water for injection, 45 mg sodium chloride, and buffered at approximately pH 5.5 with glacial acetic acid and 8.2 mg sodium acetate trihydrate. KEPPRA injection must be diluted prior to intravenous infusion. Mention type of primary packaging material.
	Decision: Deferred for submission of type of primary packaging material for applied formulation.	
2277.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019

	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Tamlev 100mg/ml oral Solution of Medisure Lab. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is solution you have applied for syrup, clarify.
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2278.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R&I & Fee	Dy.No 9040 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 250mg of M/s Akson Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2279.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 9039 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 500mg of M/s Akson Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2280.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 2.5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…2.5mg

	Diary No. Date of R&I & Fee	Dy.No 5903 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2281.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5904 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2282.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 10mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…10mg
	Diary No. Date of R&I & Fee	Dy.No 5905 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	

2283.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 10mg
	Composition	Each Tablet Contains: Bisoprolol…10mg
	Diary No. Date of R&I & Fee	Dy.No 9102 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolol fumarate 10mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 10mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2284.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 2.5mg
	Composition	Each Tablet Contains: Bisoprolol…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 9100 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 2.5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 2.5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2285.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 5mg
	Composition	Each Tablet Contains: Bisoprolol…5mg salt?
	Diary No. Date of R&I & Fee	Dy.No 9101 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019

	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2286.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Vorizole Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R&I & Fee	Dy.No 6790 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	JP Specification
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc) (film coated)
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2287.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mislip Tablet 100mg
	Composition	Each uncoated tablet contains: Amisulpride…100mg
	Diary No. Date of R&I & Fee	Dy.No 6337 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Ampisol 100mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2288.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan

	Brand Name + Dosage Form + Strength	Mislip Tablet 50mg
	Composition	Each uncoated tablet contains: Amisulpride…50mg
	Diary No. Date of R&I & Fee	Dy.No 6336 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Me-too status	Ampisol 50mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2289.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti-arthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board decided to approve registration of applied formulation for only hip and knee arthritis.	
2290.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Cancemos 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Capecitabine …500mg"
	Diary No. Date of R&I & Fee	Dy.No 4886 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Pyrimidine analogues
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	120's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Citabin 500mg tablet of m/s. Revive health care
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility.	

2291.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Salmos Syrup 2mg/5ml
	Composition	Each 5ml contains: Salbutamol as sulphate…2mg
	Diary No. Date of R&I & Fee	Dy.No 5323 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Wintol syrup of Lisko
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	*MHRA: 100 ml, 150 ml and 200 ml type III amber glass bottle with Pilfer-Proof cap, screw cap or Child resistant closure. 100 ml and 150 ml HDPE bottle with screw cap, tamper evident cap or child resistant closure
	Decision: Approved as per innovator's specification.	
2292.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg Capsule
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 5325 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's,7's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fiscon capsule 50mg of Fassgen
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2293.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 200mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…200mg"
	Diary No. Date of R&I & Fee	Dy.No 5327 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	1's, 4's, 7's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fcozole 200mg capsule of Medicraft
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2294.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 150mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…150mg"
	Diary No. Date of R&I & Fee	Dy.No 5326 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's, 7's,: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Flu-Z Capsule 150mg of Z-JANS Pharmaceuticals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2295.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg/5ml Suspension (DRY)
	Composition	Each 5ml contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 7274 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	35ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in MHRA(powder for oral suspension)
	Me-too status	Flucal of caliph pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferrred for confirmation of manufacturing facility i.e., "Dry powder suspension" section for applied formulation and revision of label claim.	
2296.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…50mg
	Diary No. Date of R&I & Fee	Dy.No 6784 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019

	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 50 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2297.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…100mg
	Diary No. Date of R&I & Fee	Dy.No 6785 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 100 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2298.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Velkeno 2.5mg/5ml Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 5329 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	30ml, 60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Limited (Reg. #054519)
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2299.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg

	Diary No. Date of R&I & Fee	Dy.No 9050 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2300.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R&I & Fee	Dy.No 9051 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2301.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 100mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…100mg
	Diary No. Date of R&I & Fee	Dy.No 9052 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Lipride tablet 100mg of Polyfine chemicals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2302.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 80mg/12.5mg Tablet

	Composition	Each Film Coated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5330 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with reference
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2303.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 40mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5331 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2304.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R&I & Fee	Dy.No 9065 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 20mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2305.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 9066 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 40mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2306.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 9067 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 80mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2307.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 40/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9098 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2308.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 80/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9099 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2309.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Mefalgic 50mg/5ml Suspension
	Composition	Each 5ml contains: Mefenamic Acid…50mg
	Diary No. Date of R&I & Fee	Dy.No 5328 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SSRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Constel 50mg/5ml suspension
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	MEntion type of primary packaging material Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following:	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Mention type of primary packaging material for applied formulation.**	
2310.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gesic 250mg Tablet
	Composition	Each Tablet Contains: Mefenamic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 7306 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Genston of Genome Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2311.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Secobal 500mcg Tablet
	Composition	Each Film Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R&I & Fee	Dy.No 5324 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's, 100's: as per SRO
	Approval status of product in reference regulatory authorities	PMDA Approved (but sugar coated)
	Me-too status	081876; Brand Name: Heam 500 mcg Tablet Manufacturer Name: Linear Parma,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for confirming film coating approval status in reference regulatory authorities.	
2312.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 600mg/2ml
	Composition	Each 2ml contains: Lincomycin as HCL…600mg
	Diary No. Date of R&I & Fee	Dy.No 5939 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	(2ml)::As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lincowrd 600mg Injection of Welwrd Pharmaceutical
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for justification on scientific grounds for not performing terminal sterilization of applied formulation.	
2313.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 300mg/ml
	Composition	Each ml contains: Lincomycin as HCL…300mg
	Diary No. Date of R&I & Fee	Dy.No 5938 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 5's, 10's(1ml): Rs.60/-, Rs.300/-, Rs.600/-, or as per SRO
	Approval status of product in reference regulatory authorities	Approved In USFDA***(could not be not confirmed in applied volume i.e. 1 ml)***
	Me-too status	Farcocine Injection of Farmaceutics Int. Karachi
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Deferred for evidence of approval of applied formulation in applied volume i.e. "1ml" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2314.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Tablets 400mg
	Composition	Each uncoated tablet contains: Doxofylline…400mg
	Diary No. Date of R&I & Fee	Dy.No 5945 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2315.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 300mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…300mg
	Diary No. Date of R&I & Fee	Dy.No 5949 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	20's, 30's: As per SRO
	Me-too status	
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…300mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2316.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 150mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…150mg
	Diary No. Date of R&I & Fee	Dy.No 5948 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Butrin XL 150mg tablet of Genome
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…150mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2317.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R&I & Fee	Dy.No 5906 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexipin 200mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2318.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R&I & Fee	Dy.No 5907 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexfen 300mg tablet of Hygeia
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2319.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R&I & Fee	Dy.No 5908 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:as per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexipin 400mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2320.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Aronic Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Ibandronate Sodium Monohydrateequivalent to ibandronic acid…150mg
	Diary No. Date of R&I & Fee	Dy.No 5943 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	bisphosphonate
	Type of Form	Form-5

	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	1's, 3's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Boonset of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2321.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Uro Trate Tablet 10meq
	Composition	Each extended release tablet contains: Potassium citrate…10meq
	Diary No. Date of R&I & Fee	Dy.No 5942 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	urinary alkalinizing agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,20's'30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Urocit-K 10meq Tablets Of Universal Enterprises
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2322.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Onvin Syrup 4mg
	Composition	Each 5ml contains: Ondansetron as Hcl dihydrate…4mg
	Diary No. Date of R&I & Fee	Dy. No 5941 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	50ml, 60ml,120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Not verifiable
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2323.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Valrate Oral Solution 250mg/5ml
	Composition	Each 5ml of oral syrup contains: Sodium valproate eq to valporic acid…250mg
	Diary No. Date of R&I & Fee	Dy. No 5940 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dipodium of 250mg/5ml syrup of Lexicon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Evidence of approval status of product in reference regulatory authorities is required. Clarification regarding physical form of applied drug product is required (syrup or solution?)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2324.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Baymil Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Bamifylline…600mg
	Diary No. Date of R&I & Fee	Dy.No 6780 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Bamiscot of scottmann
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.	
2325.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per indications approved by reference regulatory authorities.	
2326.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Barresten HC Cream 10/10mg
	Composition	Each gram contains: Clotrimazole…10mg Hydrocortisone acetate eq to Hydrocortisone…10mg
	Diary No. Date of R&I & Fee	Dy.No 6718 dated 15-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiinfectives And Antiseptics

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Razole Cream of Ciba Pharmaceuticals, Karachi . .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2327.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Nitazoxanide…500mg
	Diary No. Date of R&I & Fee	Dy.No 6788 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Izato 500mg tablet of Sami
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2328.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Dry Powder Oral suspension 100mg/5ml
	Composition	Each 5ml contains when reconstituted: Nitazoxanide…100mg
	Diary No. Date of R&I & Fee	Dy.No 6789 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30ml, 60ml; As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nitranex 100mg/5ml of Nexus Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2329.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 40mg
	Composition	Each enteric Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…40mg
	Diary No. Date of R&I & Fee	Dy.No 6799 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019

	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	7's, 10's, 14's, 20's,28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Nexium tablets
	Me-too status	Zimol 40 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2330.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 40mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate e to Ziprasidone…40mg
	Diary No. Date of R&I & Fee	Dy.No 6796 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Zpras 40mg Capsule of Wellborne Pharmachem
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2331.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zitra Tablet 30mg
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R&I & Fee	Dy.No 6794 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	ANTIDEPRESSANTS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	20's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Zepidep Tablet 30mg of Saydon Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2332.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Torek Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg
	Diary No. Date of R&I & Fee	Dy.No 6793 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	NSAID

	Type of Form	Form-5
	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2333.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Pirament Syrup 1gm(liq)
	Composition	Each 5ml contains: Piracetam……1gm
	Diary No. Date of R&I & Fee	Dy.No 6786 dated 15-02-2019 Rs.20,000/-
	Pharmacological Group	N06BX: Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Greytone 1000mg/5ml suspension of High-Q
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2334.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…20mg
	Diary No. Date of R&I & Fee	Dy.No 6798 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	7's, 10's,14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved MHRA
	Me-too status	Zimol 20 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2335.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 80mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate eq. to Ziprasidone…80mg
	Diary No. Date of R&I & Fee	Dy.No 6797 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019

	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,14's,20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ziprox 80mg Capsule of Nabiqasim Industries
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2336.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 30mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…30mg Source : Vision but stability is not submitted
	Diary No. Date of R&I & Fee	Dy.No 6792 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 30mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2337.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 15mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…15mg Source : Vision but stability is not submitted
	Diary No. Date of R&I & Fee	Dy.No 6791 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 15mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2338.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Quitapine ST Tablets 300mg

	Composition	Each extended release film coated tablet contains: Quetiapine fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 6795 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Qusel XR 300mg Tablet of Hilton Pharma Karachi . .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Quetiapine as fumarate…300mg extended release tablet.
	Decision: Deferred for submission of lable claim/composition of applied formulation in line with reference product i.e. Quetiapine as fumarate…300mg extended release tablet.	
2339.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Carbofer Injection 500mg/10ml
	Composition	Each 10ml ampoule contains: Iron as ferric carboxymaltose…500mg
	Diary No. Date of R&I & Fee	Dy.No 6977 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA (vial) Ferinject Injectable.Each 10ml vial contains:-
	Me-too status	Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2340.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Drospa Fort Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Drotaverine HCL…80mg
	Diary No. Date of R&I & Fee	Dy.No 6961 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	antispasmodic drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA italy
	Me-too status	Relispa Forte Tablets of Searle Pakistan, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2341.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Actirin Capsule 25mg
	Composition	Each Capsule Contains: Acitretin…25MG
	Diary No. Date of R&I & Fee	Dy.No 6964 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	NEOTIGASON CAPSULE 25mg Of MULLER &PHIPPS KARACHI
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2342.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acitirin Capsule 10mg
	Composition	Each Capsule Contains: Acitretin…10MG
	Diary No. Date of R&I & Fee	Dy.No 6963 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	7's, 10's, 14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	ACT 10mg Capsule of Ciba Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2343.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 100mg
	Composition	Each uncoated tablet contains: Clozapine…100mg
	Diary No. Date of R&I & Fee	Dy.No 6760 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's,50's, 60's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ekloz 100 mg Tablets of WnsFeild Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	

	Decision: Approved.	
2344.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Capsule 40mg
	Composition	Each Capsule Contains: Omeprazole as enteric coated pellets, 8.5%...40mg Source: Vision
	Diary No. Date of R&I & Fee	Dy.No 6956 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2345.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Insta Plus Sachet
	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R&I & Fee	Dy.No 7534 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ruling + Sachet of High-Q,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2346.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 500mg/ml
	Composition	Each ml contains: Cefpirome Sulfate …500mg
	Diary No. Date of R&I & Fee	Dy.No 8469 dated 26-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	CEFROM INJECTION 0.5GM of HOECHST MARION ROUSSEL KARACHI
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.

	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …0.5gm. Mention type of primary packaging material.
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	
2347.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 1gm/ml
	Composition	Each ml contains: Cefpirome Sulfate …1gm
	Diary No. Date of R&I & Fee	Dy.No 8470 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	ANSM (France) By M/s Saofi Aventis France.
	Me-too status	Cefrom Injection 1gm by M/s Sanofi Aventis (Reg#021124)
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …1gm
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	
2348.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 1.5gm/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…1.5gm
	Diary No. Date of R&I & Fee	Dy.No 8442 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 1.5 g of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 1.5mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…1.5gm**	
2349.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 750mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…750mg
	Diary No. Date of R&I & Fee	Dy.No 8441 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO

	Approval status of product in reference regulatory authorities	Zinacef 750 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 750mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…750mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…750mg**	
2350.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 250mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…250mg
	Diary No. Date of R&I & Fee	Dy.No 8440 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 250 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 250mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…250mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…250mg**	
2351.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox 125mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Cefuroxime Axetil…125mg
	Diary No. Date of R&I & Fee	Dy.No 8467 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Purox 125mg/5ml Dry Suspension of M/s ARP (Pvt) Ltd,
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product is approved as Cefuroxime as axetil…125mg per 5ml suspension.
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each 5ml contains:** **Cefuroxime (as axetil)…125mg**	

2352.	**Deleted: Duplication of Case No.2351**	
2353.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 3mg Tablet
	Composition	Each Tablet Contains: Paliperidone…3mg
	Diary No. Date of R&I & Fee	Dy.No 7276 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2354.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 6mg Tablet
	Composition	Each Tablet Contains: Paliperidone…6mg
	Diary No. Date of R&I & Fee	Dy.No 7277 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2355.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 1.5mg Tablet
	Composition	Each Tablet Contains: Paliperidone…1.5mg
	Diary No. Date of R&I & Fee	Dy.No 7275 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 14's, 28's: As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Palitec XR 1.5mg Tablet of Pharmatec Karachi . .
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2356.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 25mg
	Composition	Each uncoated tablet contains: Clozapine…25mg
	Diary No. Date of R&I & Fee	Dy.No 6959 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Amlepo 25mg Tablet of Amarant
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2357.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Itradex Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole…100mg (IR Pellets) Source: vision
	Diary No. Date of R&I & Fee	Dy.No 8188 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	4's, 8's, 12's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2358.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 67mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…67mg
	Diary No. Date of R&I & Fee	Dy.No 8185 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019

	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Corfibrate 67mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2359.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Detora Tablet 5mg
	Composition	Each film coated release tablet contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8184 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 100's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lyon 5mg Tablets of Fassgen Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2360.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 4mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…4mg
	Diary No. Date of R&I & Fee	Dy.No 8129 dated 25-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs),
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Canex 4mg Tablets of Wellborne Pharmachem and Biologicals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2361.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan

	Brand Name + Dosage Form + Strength	Ilop 1mg Tablet
	Composition	Each Tablet Contains: Iloperidone …1mg
	Diary No. Date of R&I & Fee	Dy.No 7278 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	ILOPER 1mg Tablet of Hilton
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2362.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac C 32mg/25mg Tablet
	Composition	Each film coated Tablet Contains: Candesartan…32mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy. No 8130 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Advantec Tablet of Getz Pharma Karachi
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for the following: **Mention salt form of API "Candesartan" in applied formulation along with submission of requisite fee in line with reference product.**	
2363.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 8mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…8mg
	Diary No. Date of R&I & Fee	Dy.No 8127 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 8mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018

		Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2364.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 16mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…16mg
	Diary No. Date of R&I & Fee	Dy.No 8128 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 16mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2365.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Mednir 250mg/5ml dry powder suspension
	Composition	Each 5ml contains: Cefdinir…250mg
	Diary No. Date of R&I & Fee	Dy.No 8474 dated 26-02-2019 Rs.20,000/- ated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cefnir 250mg/5ml Dry Suspension of Barrett Hodgson Pakistan
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications.	
2366.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Viptin 50mg Tablet
	Composition	Each Tablet Contains: Vildagliptin…50mg

	Diary No. Date of R&I & Fee	Dy.No 7297 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hypoglycemic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Vilda 50mg of M/s. Rotex Pharma (Pvt) Ltd, Islamabad
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2367.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 200mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…200mg
	Diary No. Date of R&I & Fee	Dy.No 8186 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Corfibrate 200mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2368.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ciricode syrup for oral soultion 100mg
	Composition	Each ml contains: Citicoline as Sodium…100mg
	Diary No. Date of R&I & Fee	Dy.No 6965 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30ml, 60ml,120ml: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Cercolin Syrup of M/s Schazoo Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2369.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 20mg Tablet

	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…20mg
	Diary No. Date of R&I & Fee	Dy.No 9058 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10,s: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2370.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…40mg
	Diary No. Date of R&I & Fee	Dy.No 9059 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2371.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 100mg Capsules
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R&I & Fee	Dy.No 9044 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 100mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2372.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Gabreg 300mg Capsules
	Composition	Each Capsule Contains: Pregabalin…300mg
	Diary No. Date of R&I & Fee	Dy.No 9046 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 300mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2373.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9075 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiinfectives and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)
	Me-too status	Robecide 200 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee.** **Updated status of GMP from QA & LT Division.**	
2374.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…400mg
	Diary No. Date of R&I & Fee	Dy.No 9076 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)

	Me-too status	Robecide 400 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee. **Updated status of GMP from QA & LT Division.**	
2375.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 400mg Tablet
	Composition	Each Tablet Contains: Linezolid…400mg
	Diary No. Date of R&I & Fee	Dy.No 9053 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(zyvox tablet 400mg) (but discontinued, however it is written that Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Barizold tablet 400mg of Barrett Hodgson(Reg #076342)
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2376.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…600mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	LinzolTablet 600 mg of M/s Regal Pharmaceuticals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is film coated tablet
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2377.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Gabreg 75mg Capsules
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Regab of Caraway pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2378.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Azonax 0.25mg Tablet
	Composition	Each film coated Tablet Contains: Alprazolam…0.25mg
	Diary No. Date of R&I & Fee	Dy.No 9037 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Medilap 0.25mg Tablet of Wellborne Pharmachem and Biologicals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of required manufacturing facility "Tablet psychotropic section" from licensing division.** **Updated status of GMP from QA & LT Division.**	
2379.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 500mg Tablet
	Composition	Each Tablet Contains: Mebendazole…500mg
	Diary No. Date of R&I & Fee	Dy.No 9072 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTINEMATODAL AGENTS
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Leukiban Tablets 100mg of Rakaposhi Pharmaceuticals (Pvt) Ltd.,

	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2380.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Viredo B Tablet 300mg
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil as Fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 9061 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	
	Me-too status	
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2381.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 9041 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Levetiracetam Thame 100mg/ml Oral Solution
	Me-too status	Levefil Oral Solution of Pharmatec Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2382.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Suspension 200mg/5ml
	Composition	Each 5ml of suspension contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9074 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO

	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Mogel 200mg Suspension of M/s Metro Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2383.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 50mg Capsules
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R&I & Fee	Dy.No 9042 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dygab 25mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2384.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 50mg Tablet
	Composition	Each Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but outline of method of manufacturing do not contain step of coating.	
2385.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 75mg Tablet

	Composition	Each film coated Tablet Contains: Diclofenac potassium…75mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2386.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lowstat 10mg Tablet
	Composition	Each Tablet Contains: Simvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 7304 dated 20-02-2019 Rs.20,000/-
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(film coated tablet)
	Me-too status	Mistin 10mg Tablet of Mission Pharma.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2387.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hcl…10mg
	Diary No. Date of R&I & Fee	Dy.No 7296 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	

	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2388.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 10mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 9092 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Save-R Tablets 10mg of Wilson's Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…10mg film coated tablet.
	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 10mg in a tablet.** • **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2389.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…20mg
	Diary No. Date of R&I & Fee	Dy.No 9093 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Registration Number 080326 Brand Name Restore 20mg Tablet (Rosuvastatin calcium) Manufacturer Name Mission Kar. Manufacturer Address Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…20mg film coated tablet.

	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 20mg in a tablet.** • **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2390.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Moxibax 400mg Tablet
	Composition	Each Tablet Contains: Moxifloxacin Hcl…400mg
	Diary No. Date of R&I & Fee	Dy.No 7309 dated 20-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Avelox 400mg film-coated tablets byM/s Bayerplc,
	Me-too status	Molinza tablet 400mg M/S Zafa
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Moxifloxacin as Hcl…400mg film coated tablet. Master Formulation contains ingredients of coating
	Decision: Deferred for the following: **Submission of Form 5, master formulation, manufacturing method after correction in line with reference product Moxifloxacin as Hcl 400mg film coated tablet.**	
2391.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Atenox Tablet 25mg
	Composition	Each Tablet Contains: Atenolol…25mg
	Diary No. Date of R&I & Fee	Dy.No 9096 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	BETA BLOCKING AGENTS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(uncoated tablet)
	Me-too status	Atomin 25mg Tablet of Semos Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Master Formulation contains ingredients of coating
	Decision: Deferred for the following: **Submission of master formulation after correction in line with reference product Moxifloxacin as Hcl…….400mg film coated tablet.**	
2392.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Desodine 5mg Tablet
	Composition	Each film coated tablet Contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9089 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE

	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet. MF contains ingredients of coating
	Decision: Approved with innovator's specifications.	
2393.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Salazo-En 500mg Tablet
	Composition	Each Tablet Contains: Sulfasalazine…500mg
	Diary No. Date of R&I & Fee	Dy.No 7295 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Zalaz Tablets of Mediate Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as enteric coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Deferred for revision of formulation as per reference product alongiwth requisite fee.	
2394.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart Tablet 80mg
	Composition	Each Film coated tablet Contains: Valsartan…….80mg
	Diary No. Date of R&I & Fee	Dy.No 9091 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Valsartan 80mg Film-coated Tablets (MHRA Approved)
	Me-too status	Valseta 80mg Tablet by Maple Pharma (Reg#83347)
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	MF contains ingredients of coating.
	Decision: Approved .	
2395.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 100mg/5ml(dry)

	Composition	Each 5ml contains: Mebendazole…100mg
	Diary No. Date of R&I & Fee	Dy.No 9073 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antinematodal agents
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	30ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc)
	Me-too status	Nemazole Suspension of M/s Nexus Pharma
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Revision of formulation from dry suspension to liquid suspension alongwith submission of requisite fee.** **Updated status of GMP from QA & LT division.**	
2396.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hydrochloride……..…10mg
	Diary No. Date of R&I & Fee	Dy.No 9090 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Registration Board decided to reject the application as same formulation with same brand name is considered in the name of M/s Baxter Pharmaceuticals at serial No. 2387.	
2397.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fyprox CR Tablet 25mg Fyprox CR Tablet 12.5mg
	Composition	Each enteric film coated tablet contains: Paroxetine as Hydrochloride……..…25mg
	Diary No. Date of R&I & Fee	Dy.No 7539 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Deroxat CR tablet 25mg by Global Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	• Submit composition/label claim of applied formulation in line with product approved in reference agencies i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for submission of composition/label claim and manufacturing method for applied formulation in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 25 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2398.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Oltal F Capsule 3mg/25mg
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine HCL eq to Fluoxetine…25mg
	Diary No. Date of R&I & Fee	Dy.No 7540 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Symbyax 3 mg/25 mg Capsules of Eli Lilly , USA (USFDA)
	Me-too status	Olanzo-F 3/25 mg Capsules of Regal pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2399.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ploro T Injection 40mg/0.04mg
	Composition	Each 4ml ampoule contains: Pholoroglucinol hydrated…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R&I & Fee	Dy.No 7536 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	antispasmodic agent
	Type of Form	Form-5
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	(4ml) 6's: As per SRO
	Approval status of product in reference regulatory authorities	Phloroglucinol/Trimethylphloroglucinol Arrow 40 mg / 0.04 mg per 4 ml, solution for injection by M/s GENERIC ARROW, ANSM France
	Me-too status	Anafortan Plus Injection 40mg/0.04mg (4ml ampoule) by M/s Ali Gohar Pharmaceuticals (Pvt) Ltd, Reg. No. 24503
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2400.	**Name and address of manufacturer / Applicant**	**"M/s Walt Danzay Pharmaceuticals. 35-A, Punjab, Small Industrial Estate,Taxila, Paksitan"**
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% Injection

	Composition	Sodium Chloride 0.9% Injection Each ml Ampoule Contains: Sodium Chloride…0.9%w/v"
	Diary No. Date of R& I & fee	Dy.No.21048 dated 12-06-2018 Rs.20,000/-
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's (5ml), (10ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Norsal 0.9% Infusion of Nabiqasim Industries
2401.	GMP status	
	Remarks of Evaluator	• Justification on scientific basis for addition of 3% overage in applied formulation. • Mention quantity of sodium chloride in one ml & submit master formulation accordingly. • Submit separate application for each applied volume. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility & Submit latest GMP inspection report.
	Decision: Registration Board decided to reject the application since DML in the name of M/s Walt Danzy Pharmaceuticals is not valid.	
2402.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Palidol 6mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…6mg"
	Diary No. Date of R& I & fee	Dy.No. 21235 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2403.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"

	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2404.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 5mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No. 21242 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO Rs.182/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nebilol 5mg Tablet of Genix Pharma Karachi
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2405.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson10mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21243 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.300/-

	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2406.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 2.5mg Tablet
	Composition	"Each film coated tablet Contains: Nebivolol (as hydrochloride)…2.5mg"
	Diary No. Date of R& I & fee	Dy.No. 21241 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.108/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 2.5mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2407.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Diabet 50mg Tablet
	Composition	"Each Tablet Contains: Vildagliptin…50mg"
	Diary No. Date of R& I & fee	Dy.No. 21239 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	28's:As per SRO or Rs.1471.08/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Galvus Tablets 50mg Of Novartis Pharma
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.

	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2408.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Deferred for submission of evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2409.	**Deleted: Duplication of case at Serial No. 2404**	
2410.	**Deleted: Duplication of case at Serial No. 2405**	
2411.	**Deleted: Duplication of case at Serial No. 2406**	
2412.	**Deleted: Duplication of case at Serial No. 2407**	
2413.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Terbi Aid 250mg Tablet
	Composition	"Each tablet contains: Terbinafine(as hydrochloride)…250mg"
	Diary No. Date of R& I & fee	Dy.No.21655 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg of M/sNeomedix Pharmaceuticals
	GMP status	
	Remarks of Evaluator	Fee challan is for Terbi Aid 250mg Capsule instead of Terbi Aid 250mg Tablet. Clarification regarding applied formulation is coated or uncoated.
	Decision: Deferred for the following: • **Clarification regarding applied formulation is coated or uncoated.** • **Submit Fee challan for relevant formulation.**	

2414.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Isonic 20mg Capsule
	Composition	"Each hard gelatin capsule contains: Isotretinoin…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21656 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Retinoid for topical use in acne
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	5's, 10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Atractin20mg Capsule of Genome
	GMP status	GMP inspection conducted on 16-03-2017 concluded that firm is operating at good level of GMP compliance.
	Remarks of Evaluator	Evidence of section approval & equipment used in manufacturing of applied formulation is required. Applied formulation is hard shell capsule stability studies may be needed.
	Decision: Deferred for the following: • **Evidence of section approval & equipment used in manufacturing of applied formulation is required.** • **Applied formulation is hard shell capsule so submit stability studies as per guidelines approved in 293rd meeting of Registration Board.**	
2415.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan By Medisure Lab Pvt Ltd"**
	Brand Name +Dosage Form + Strength	Iroaid 100mg/5ml Injection
	Composition	"Each 5ml contains: Iron sucrose eq. to elemental Iron….100mg"
	Diary No. Date of R& I & fee	Dy.No. 20883 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Acron S 100mg/5ml Injection of Asian Continental
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.** • **Mention type of primary packaging material of applied formulation.**	

2416.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan By Medisure Lab Pvt Ltd"**
	Brand Name +Dosage Form + Strength	Seafix 100mg/5ml Suspension
	Composition	"Each 5ml contains: Cefixime (as trihydrate)….100mg"
	Diary No. Date of R& I & fee	Dy.No 20882 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status (with strength and dosage form)	Seaxim Dry Suspension of Semos Pharmaceuticals
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for type of primary packaging material of applied formulation.	
2417.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine(as hydrobromide)…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21069 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2418.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 97/103 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan…103mg"

	Diary No. Date of R& I & fee	Dy.No.21065 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Neprilysin Inhibitors ,angiotensin receptor blocker,
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2419.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Lacomide 10mg/ml Syrup
	Composition	"Each ml Contains: Lacosamide…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21067 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Anti-epileptic drug
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	60ml,90ml,120ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in Belgium, Germany, Ireland, Malta & UK
	Me-too status (with strength and dosage form)	Lalap syrup 10mg/ml by Genix Pharma (Reg#089376)
	GMP status	Panel Inspection for renewal of DML conducted on 18th & 31st July recommended grant of renewal of DML.
	Remarks Of Evaluator	Applied formulation is new molecule for which submission of stability studies & fee Rupee 50,000 is required.
	Decision: Approved.	
2420.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 49/51 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg"
	Diary No. Date of R& I & fee	Dy.No.21066 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA

	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks Of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2421.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 24/26 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…24mg Valsartan…26mg"
	Diary No. Date of R& I & fee	Dy.No. 21064 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	------
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2422.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine (as hydrobromide)…10mg"
	Diary No. Date of R& I & fee	Dy.No.21070 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed

	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2423.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Palidol 3mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…3mg"
	Diary No. Date of R& I & fee	Dy.No.21234 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2424.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 12.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No. 30866 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).

	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	
2425.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 25mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 30867 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	
2426.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 37.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 30868 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018

	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	

Case no. 02 Registration applications of categories to be considered on priority

a. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

2427.	**Deleted as the case was already approved.**	
2428.	**Deleted as the case was already approved.**	
2429.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oranib 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sorafenib as tosylate…200mg"
	Diary No. Date of R& I & fee	Dy.No 4887 dated 02-02-2019 Rs.20,000/-
	Pharmacological Group	Kinase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications
	Pack size & Demanded Price	10's, 30's, 60's, 120's, :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	NEXAVAR 200MG TABLETS of BAYER PAKISTAN
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.

	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing facility.	
2430.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Semotrozole 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Anastrozole…….1mg"
	Diary No. Date of R& I & fee	Dy.No 4885 dated 04-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications
	Pack size & Demanded Price	10's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	ARMOTRAZ TABLETS 1mg Of AJ MIRZA PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2431.	Name and address of manufacturer / Applicant	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha
	Brand Name +Dosage Form + Strength	Lozet 2.5mg Tablet
	Composition	Each Film Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No 5180 dated 06-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2432.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tomifen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Tamoxifen Citrate…10mg
	Diary No. Date of R& I & fee	Dy.No 5155 dated 06-02-2019 Rs.20,000/-
	Pharmacological Group	Anti-oestrogen
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(EQ 10MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	
	GMP status	Dated: 10-07-2019 **Concluding Remarks:** Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator.	Reference product is approved as Tamoxifen as citrate 10mg uncoated tablet.
	Decision: Deferred for the following : **Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. Tamoxifen as citrate 10mg uncoated tablet. Along with submission of requisite fee, master formulation & manufacturing method.**	
2433.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neoplaxol 100mg/5ml Injection
	Composition	Each 5ml ampoule contains: Etoposide as phospate…100mg
	Diary No. Date of R& I & fee	Dy.No 5592 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (5ml):As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	SEDOL 100MG/5ML INJECTION of Helix
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2434.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Irotec 300mg Injection
	Composition	Each ml contains: Irinotecan Hcl Trihydrate…20mg
	Diary No. Date of R& I & fee	Dy.No 5587 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Other antineoplastic agents

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (15ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	IRINOTECAN EBEWE 100MG/5ML of Novartis
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2435.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 80mg/2ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous 80mg polysorbate…80 qs 2ml
	Diary No. Date of R& I & fee	Dy.No 5589 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA Aproved in USFDA (40MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	TAXOTERE INFUSIONEACH VIAL CONTAINS DOCETAXEL TRIHYDRAT (AS ANHYDROUS) 80MG, POLYSORBATE 80PB Q.S TO 2ML of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision: Deferred for the following: • **Justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Status of Diluent whether it is combo pack or otherwise.**	
2436.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rubidox P 50mg/25ml Injection
	Composition	Each ml contains: Doxorubicin hydrochloride…2mg

		(as lposomalpegylated)
	Diary No. Date of R& I & fee	Dy.No 5607 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Anthracyclines and related substances
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(25ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2437.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 20mg/0.5ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous… 20mg polysorbate…80 qs 0.5ml
	Diary No. Date of R& I & fee	Dy.No 5595 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(0.5ml) vial: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	TAXOTERE I.V. INFUSIONE of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Submit separate application for diluent.**	
2438.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cisplat 50mg/100ml Injection
	Composition	Each ml contains: Cisplatin…0.5mg
	Diary No. Date of R& I & fee	Dy.No 5608 dated 07-02-2019 Rs.20,000/-

	Pharmacological Group	Platinum compounds
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's (100ml vial): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	QUIRAL QUIMICA of NEOMEDIX RAWALPINDI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2439.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Menocar Tablets 2.5mg
	Composition	Each Film Coated Tablet Contains: Letrozole …2.5mg
	Diary No. Date of R& I & fee	Dy.No 5369 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	Rs.291.66/tablet, Rs. 8750/ 30tablets: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 18-10-2019 Certificate of GMP issued on 18-10-2019.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2440.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, KotLakhpat, Lahore
	Brand Name +Dosage Form + Strength	Virin 4 Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy.No 5334 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's,40's,50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Revirin-C tablet of High-Q
	GMP status	Dated: 27-08-2018, 05-10-2018, 06-11-2018 **Recommendations:** The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.

	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2441.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 200mg Tablets
	Composition	Each Tablet Contains: Acyclovir…200mg
	Diary No. Date of R& I & fee	Dy.No 5802 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Anti viral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Clovir 200 mg Tablets of Glitz Pharam, Kahuta Road P.No.265, Industrial Triangle, Islamabad
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2442.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 800mg Tablet
	Composition	Each Tablet Contains: Acyclovir…800mg
	Diary No. Date of R& I & fee	Dy.No 5804 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,15's,20's,25's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Virocyc Tablets of Global Pharmaceuticals
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and

		facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2443.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 400mg Tablet
	Composition	Each Tablet Contains: Acyclovir…400mg
	Diary No. Date of R& I & fee	Dy.No 5803 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Cyclor Tablets of Candid Pharmaceuticals,
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2444.	Name and address of manufacturer / Applicant	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan-75700
	Brand Name +Dosage Form + Strength	Ovara 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 5902 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 11-05-2018 **Conclusion:**

		Based on the areas visited, people met and commitment of the firm for continuous improvement. It is concluded that the firm is operating at a **Good level of GMP compliance** at the time of inspection.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2445.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 250mg
	Composition	Each dispersible tablet contains: Deferasirox…250mg
	Diary No. Date of R& I & fee	Dy.No 6958 dated 19-02-2019 Rs.20,000/-
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	Dated: 20-09-2017 Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2446.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 500mg
	Composition	Each dispersible tablet contains: Deferasirox…500mg
	Diary No. Date of R& I & fee	Dy.No 6957 dated 19-02-2019 Rs.20,000/
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	ODEROX -500 DISPERSIBLE TABLET of M/S. AJ MIRZA PHARMA (PVT) LTD.,
	GMP status	Dated: 20-09-2017 Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	

	Decision: Approved as per innovator's specification.	
2447.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oxy Z 500mg Capsule
	Composition	Each Capsule Contains: Hydroxyurea…500mg
	Diary No. Date of R& I & fee	Dy.No 8123 dated 25-02-2019 Rs.20,000/-
	Pharmacological Group	Antimetabolite
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	1's, 10's, 1000's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	HYDAB 500MG CAPSULE of ATCO PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of required manufacturing facility.	

Case no. 03 Registration applications of import cases

a. New Cases (Human)

2448.	Name and address of Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. House # 166-A, Street # 9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name and address of marketing authorization holder	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No. 31977 dated 25-09-2018 Rs.100,000/- Dated 25-09-2018
	Fee including differential fee	Rs.50,000/- Dated 21-05-2018
	Brand Name +Dosage Form + Strength	Calderol 1mcg/ml Solution for IV Injection
	Composition	"Each ml Contains: Calcitriol……..1mcg"
	Finished Product Specification	Manufacturer's specifications
	Pharmacological Group	Vitamin D analogue
	Shelf life	36 months as per the stability study data of the product conducted as per conditions of zone IV-B
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Approved in USFDA
	Me-too status	
	Detail of certificates attached	CoPP (No. 2018/2203) issued by Turkish medicines and medical devices agency dated 04-06-2018 for calderol 1mcg/ml solution for IV injection which confirms the free sale

		status of the product in country of origin as well as GMP status of the manufacturer. The certificate was valid till 04-06-2020.
	Remarks of the Evaluator	
	Decision: Approved as per the policy for inspection of manufacturer abroad. Firm will provide valid, legalized CoPP before issuance of Registration letter.	

Case No. 04 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

2449.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Sofosbuvir Tablet 400mg
	Composition	Each film coated tablet contains: Sofosbuvir…. 400mg
	Diary No. Date of R& I & fee	R&I date: 27-08-2018 Fee 20,000/- (20-08-2018) Duplicate dossier
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	28's(HDPE bottle): As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	N/A

STABILITY STUDY DATA

Drug	Sofosbuvir Tablet 400mg		
Name of Manufacturer	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.		
Manufacturer of API	Optimus Drugs PVT Limited, Factory, Sy No. 239 & 240 Dothigudam(V) Pochampally(M), Nalgonda Dist., Telangana, India		
API Lot No.	**Batch No.**OP-GLD/10/15/037		
Description of Pack (Container closure system)	28's; HDPE Bottle		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real Time: 0,4,8,12,24 MonthsAccelerated: 0,4,8,12,24 Months		
Batch No.	Tr-01	Tr-02	Tr-03
Batch Size	212 tablets	212 tablets	212 tablets
Manufacturing Date	August, 2017	August, 2017	August, 2017
Date of Initiation	22th August, 2017	22th August, 2017	22th August, 2017
No. of Batches	03		
Date of Submission	28-06-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Firm has submitted copy of COA stating following information on it: **Product:**Sofosbuvir **Batch No.**OP-GLD/10/15/037 **Manufacturer:**Optimus Drugs PVT Limited,

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted GMP certificate having following information on it: **Certificate No.**L.Dis.No.20121/A3/2018 **Issued to:**Optimus Drugs PVT Limited, **Issued on:** 21-05-2018 **Validity:** One Year From The Date Of Issue
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice stating following information on it: **Invoice No.** 412/EXP **Batch No of API.** OP-GLD/10/15/037 **Attested by Assistant Director (I & E) DRAP Karachi On** : 03-02-2016
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

SOFOSBUVIR TABLET 400MG, M/S ZAFA PHARMACEUTICALS LABORATORIES.

Following panel of inspectors visited M/s Zafa Pharmaceuticals Laboratories for verification of authenticity of submitted stability study data for registration of Sofosbuvir 400mg Tablet.

1. Syed Adnan Rizvi Director, DTL, Karachi.
2. Dr. Najam-us-Saquib Additional Director DRAP, Karachi.
3. Kirshan, Assistant Director, DRAP, Karachi.

Q.No.	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	The firm has imported Sofosbuvir from Optimus Drug Pvt. Ltd. Hyderabad INDIA, Supplier IRIS Karachi. Invoice No.412/EXP dated 15-11-2015. Batch # OP-GLD/10/15/037. The total quantityofAPI purchased was1.00 kg.The approval from DRAP is available. (Annex-A)
2.	What was the rationale behind selecting the particular manufacturer of API?	Rationale behind selecting the particular manufacturer of API, as it is GMP compliant and vendor evaluation has been done. (Annex-B).
3.	Do you have documents confirming the import of reference standard and impurity standards?	The reference standard & impurity standard were imported through Optimus Drug Pvt. Ltd. Hyderabad INDIA. In House Reference standard, Batch # OP-SFS/RS1402, quantity100mg.Impurity standard, Batch # OP-GLD/St-I/Rp-Isomer/A0453/055, with quantity 10.0mg. (Annex-C)
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has COAs for API, reference standards and impurity.

5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP Certificate of API manufacturer issued by Drug Control Administration Govt. of TelanganaINDIA.L.DisNo. 2021/A3/2018 Dated 21-05-2018.
6.	Do you use API manufacturer method of testing for testing API?	The Firm has used manufacturer's method of testing for the testing of API.
7.	Do you have stability studies reports on API?	The firm has manufacturers Stability studies report of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing as per SIM method and degradation products has been quantified by the API manufacturer.
9.	Do you have method for quantifying the impurities in the API.	The firm has used HPLC method for chromatographic impurities that was used for assay purpose.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some quantities of API (As reference), reference standard.
11.	Have you used pharmaceutical grade excipients?	The firm has used Pharmaceutical grade excipients
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records of the excipient used.
14.	Do you have written and authorized protocols for the development of applied product?	The firm has written protocol for the development of Sofosbuvir Tablets 400 mg.(Annex-D)
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed drug excipient compatibility studies because the composition of their tablets/product is similar to that of the innovator's product (Sovaldi Tablets)
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies and their product show comparable dissolution profile and same were reviewed at time of inspection.
17.	Do you have product development (R&D) section.	The firm has separate new product development (R&D) section.
18.	Do you have necessary equipments available in product development section for development of applied product?	The firm has used Quality Control Lab instruments for the development of Sofosbuvir Tablets 400 mg. The firm has all necessary equipment in QC and Product development section.
19.	Are the equipment in product development section qualified?	All the equipment used in the development of product is qualified.
20.	Do you have proper maintenance / calibration / requalification program for the equipment used in PD section?	The firm has proper maintenance and calibration for the equipment used in quality Control for the development of the product.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff for the development of the product with proper knowledge and training in product development. (Annex-E)
22.	Have you manufactured three stability batches for the stability studies of applied products required?	The firm has manufactured three stability batches, of Sofosbuvir Tablets 400 mg, TR01, TR02, TR03.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability of batches are the number of tablets as per requirement of testing.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. All the log books are properly maintained and reviewed at the time of inspection.
25.	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of the stability batches.

26.	Do you have developed and validated the method for testing of stability batches?	Yes, the firm has used manufacturer's method of testing, the method is validated.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, the firm has proper documents confirming the qualification of equipment and instruments being used in the test and analysis of API and the finished product.
29.	Do your method of analysis stability indicating?	Yes the method of analysis is stability indicating.
30.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR compliant.
31.	Can you show Audit Trail reports on Stability study testing?	The firm showed the Audit trail report on API and finished product testing.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33.	Do you have commitment batches kept on stability testing?	The firm has three commitment batches kept on stability testing for real time stability studies.
34.	Do you have valid calibration status for the equipment used in Production and analysis?	Yes, the firm has valid calibration status for the equipment used in the production and analysis of Sofosbuvir Tablets 400 mg.
35.	Do proper and continuous monitoring and control are available for stability chambers.	Continuous power supply and monitoring and control are available for the stability chambers.
36.	Do related manufacturing area, equipment, personal and utilities be used as GMP compliance	The relevant manufacturing facilities are GMP complaint.

Conclusion:

M/s Zafa Pharmaceutical Laboratories was inspected as per directions contained in DRAP letter No. 13-11/2017-PEC (Pt) dated 30th July, 2019. During inspection, the panel inspected/reviewed the relevant record, data and premises in detail with specific focus on the observations/points made in above referred letter. Following are the current observations:

1. **Criterion/reference for selection of Q Value 70%:** - The said molecules was not included in any official monograph, therefore, the firm previously performed the dissolution test as per general requirement for dissolution testing and there was no any specific criteria for the selection of Q value 70%. Now, the firm have performed dissolution test for their product according to US-FDA recommended dissolution method and found it satisfactory at the time of inspection.
2. **Valid GMPCertificate** of API Manufacturer is hereby attached for reference.
3. On the basis of risk-based approach the genuineness/ authenticity of stability data submitted by the firm for registration of Sofosbuvir Tablets 400mg is verifiable to satisfactory level.
4. The related manufacturing area, equipment, personnel and utilities observed in line as per GMP requirements and well suited for manufacturing of the said product.

Recommendations:

Based on the people met, documents reviewed and observations made during inspection including corrective action taken by the firm, the panel unanimously recommends that the firm may kindly be granted necessary registration of Sofosbuvir Tablets 400mg.

Decision(M-294): Registration Board decided to defer the case for following submissions:

- Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.
- Valid GMP certificate of the API manufacturer.

Now the applicant has submitted following:

Applicant has referred to their Comparative dissolution profile of applied formulation with reference product and submitted results declaring drug release profile of applied formulation is greater than 90 % within 15 minutes.

Decision: Registration Board keeping in view its decision taken in 293rd meeting decided to defer the case for following submissions:

- **Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.**
- **Valid GMP certificate of the API manufacturer.**

2450.	Name and address of manufacturer / Applicant	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.
	Brand Name +Dosage Form + Strength	Helisopt Ophthalmic Suspension
	Composition	Each ml ophthalmic suspension contains: Brinzolamide...……..…10mg Timolol (as maleate)…….5mg
	Diary No. Date of R& I & fee	Duplicate dossier
	Pharmacological Group	Carbonic Anhydrase Inhibitor, Beta-adrenergic blocking agent.
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP compliant dated 10-08-2017.

STABILITY STUDY DATA

Drug	Helisopt Ophthalmic Suspension		
Name of Manufacturer	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.		
Manufacturer of API	**Timolol (as maleate):** M/s. Gangwal Chemicals Pvt. Ltd., Plot No. N-5 Mide, TarapurBoisar, District: Thane 01 506, India **Brinzolamide:** M/s. Century Pharmaceuticals 103 to 106, GIDC, Halol, 389 350, Dist: PANCHMAHAL, Gujrat State, India.		
API Lot No.	**Timolol (as maleate):** (Batch No. TMM-051656. Mfg date: May 2016, Quantity: 2kgs). **Brinzolamide:** (Batch No.07111004-BA. Mfg date: March 2016, Quantity: 80grams).		
Description of Pack (Container closure system)	(5ml) LDPE bottle		
Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) Accelerated: 0,3,6 Months		
Batch No.	TF 001	TF 002	TF 003
Batch Size	01 Litters	01 Litters	01 Litters
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	25-08-2017	25-08-2017	25-08-2017
No. of Batches	03		
Date of Submission	Dy No.12219, 03-04-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	**Documents To Be Provided**	**Status**

No.		
9.	COA of API	Yes
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Timolol (as maleate):** Copy of GMP certificate bearing a number NEW-WHO-GMP/CERT/KD/50623/2016/11/17467 issued to M/s. Gangwal Chemicals by Food & Drug Administration Maharashtra, India. Valid until 02-12-2018. **Brinzolamide:** Copy of GMP certificate bearing a number 1707219 issued to M/s. Century Pharmaceuticals by Food & Drug Control Administration, Gujarat state India. Valid until 06-07-2019.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	**Timolol (as maleate):** Copy of Form 5 (license to import Drugs) issued by ADC, DRAP, Karachi dated 04-07-2016 has been submitted. Copy of commercial invoice has been submitted. **Brinzolamide:** Copy of Form 6 (license to import Drugs for clinical trial examination) issued by ADC, DRAP, Karachi dated 21-09-2016 has been submitted. Copy of ADC attested commercial invoice has been submitted.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR & REPLIES OF APPLICANT

- The firm has claimed Manufacturer's Specifications and the product is not present in available USP & BP.
- Submit raw data sheets of analytical method of applied formulation.
- Commitment to follow Drug Specification Rules, 1978.
- Commitment to continue real time stability studies till the proposed/assigned shelf life.
- Latest GMP inspection report conducted within the period of last one year.
- Chromatographic conditions in the finished product testing method submitted in dossier is different to that submitted with stability studies. Clarify/Justify.

Applicant has submitted that "We have applied for product dossier file on 20-04-2012, at that time, we did not have HPLC complies Software 21CFR but now we have all HPLCs complies with software 21CFR and we are working on HPLC with software 21CFR for new product's stability studies. Therefore you found the difference in chromatographic conditions & current chromatographic conditions upon which stability studies are performed are following: wavelength 280nm & flow rate 1ml/minute".

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Helisopt Ophthalmic Suspension (Brinzolamide/Timolol) by M/s. Helix Pharma , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 10th December, 2018.
Investigation Date and Time: 18th December, 2018 (Forenoon).
Investigation Site: Factory premises of M/s. Helix Pharma, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Helix Pharma, Karachi for registration of Helisopt Ophthalmic Suspension each ml of which contain Brinzolamide 10mg and Timolol (as maleate) 5mg and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Dr. Abdul Waheed, Assistant Director, CDL, DRAP, Karachi
2. Mr. Adnan Rizvi, Director DTL Sindh, Karachi (Member Registration Board)
3. Dr.Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Helisopt Ophthalmic Suspension

S.No.	Question	Observation by panel
1	Do you have documents confirming the import of API ?	The firm has imported 80g Brinzolamide from M/s Century Pharmaceuticals Limited, India vide invoice no. EXP16087 dated 2-09-2016 and 4.0 kg from M/s Gangwal Chemical Pvt. Ltd. India vide invoice No. EXP-T/030/16-17 dated 05.01.2017 and obtained approval from DRAP Karachi
2	What was the rationale behind selecting the particular manufacturers of APIs?	There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF etc. The firms were evaluated on above mentioned criteria and selected
3	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of both APIs USP reference standard and impurity standards.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs, working standards and their impurities.
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of Brinzolamide and timolol manufacturers issued by Food and Drug Control Administration, Gujrat State, India and Food and Drug Administration, Mahrashtra, India respectively.
6	Do you use API manufacturer method of testing?	The firm has used USP method of testing for both APIs.
7	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months on both APIs and five years and four years real time stability studies reports on the Brinzolamide and Timolol respectively.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9	Do you have method for quantifying the impurities in the API?	The firm has USP method for quantifying the impurities in the API.

<table>
<tr><td>10</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has remaining quantities of API and reference standard of both APIs.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has documents confirming the procurement of all excipients used.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of API ophthalmic suspension?</td><td>The firm has written and authorized protocols for the product development.</td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>N/A</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with equipment for manufacturing of ophthalmic suspension dosage form. The analytical part is performed on equipment of routine quality control tests.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of API ophthalimic suspension?</td><td>The firm has necessary equipment for product development of API ophthalmic suspensions. The product in question has been developed while using some equipment of commercial manufacturing also. Furthermore, the analytical part has been performed via the routine quality control equipment. Firm has already placed orders for procurement of other equipment for this section.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff which include One Chemist and One Pharmacist in product development section with relevant work experience.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of API ophthalmic suspension as required?</td><td>The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Helisopt ophthalmic suspension packed in LDPE bottles of 5ml each.
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg Date</td></tr>
<tr><td>TF 001</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 002</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 003</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
</table></td></tr>
<tr><td>23</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of bottles per testing and the number of bottles required for whole stability testing.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for stability testing of stability batches in which the stability conditions are:
Real Time: 30°C and 65% RH
Accelerated: 40°C and 75% RH,</td></tr>
</table>

		however, the firm has used LDPE container for the product in question for which ICH guidelines and WHO recommends 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies.
26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches. The method is supported by impurities standards spiking studies, forced degradation, hence capable of quantifying the degradation products in their ophthalmic suspension kept on stability testing.
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
28	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
30	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 12 months studies have been completed with satisfactory results.
34	Do you have valid calibration status for the equipment used in API ophthalmic suspensions production in analysis?	The firm has valid calibration status for the equipment used in helisopt ophthalmic suspension production and analysis.
35	Do proper and continuous monitoring and control are available for stability Chamber?	Continuous power supply and monitoring are available for stability chambers.
36	Do related manufacturing area, equipment, personnel and utilities be Rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.

Discussion:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Helisopt Ophthalmic Suspension is verifiable to satisfactory level.
2. Furthermore, the firm has conducted the stability studies as per their protocol which is 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies, whereas, the recommended stability conditions for products packed in semi-permeable containers are 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. However, 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies may be used for semi-permeable containers provided the calculated water loss multiplied with the corresponding factor may not exceed 5% of initial, which is considered as significant change.
3. In this case the firm has not calculated water loss at any stage, so no comparison can be made between the reference and alternative relative humidity as mentioned in ICH Q1A (R2) (2.2.7.3. Drug products packaged in semi-permeable containers).
4. On risk-based approach the data evaluated during inspection does not show any deviation in the critical tests throughout the study period which may be altered if the water has lost more than the prescribed limits.

5. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Helisopt Ophthalmic Suspension.

Recommendations:

The firm may be granted necessary registration of Helisopt Ophthalmic Suspension in their name with the direction to conduct stability studies on their commitment batches as per ICH guidelines i.e. 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies and submit the data to the Drug Registration Board.

Previous Decision:

Registration Board in its 287th meeting decided as follow:

Registration Board deferred the case for submission of stability data at next time point of long term stability studies along with assessment of water loss rate for applied container closure system as per ICH Q1A (R2) guidelines for "Stability Testing of New drug substances and products."

Evaluation by PEC:

Applicant has submitted results of Water loss test in the form of graphs conducted on following newly manufactured batches of applied formulation.

Sr. No.	Batch No.	Batch Size.
1.	TF004	90 bottles
2.	TF005	90 bottles
3.	TF006	90 bottles

Decision:

Deferred for submission of formula by which results of moisture loss from the semipermeable container are calculated as well as submit details of readings used to plot the graph, as only graphs are submitted.

Evaluation by PEC:

Now the applicant has submitted following:

1. Formula by which results of moisture loss from the semipermeable container are calculated.
2. Readings used to plot the graph with the conclusion that moisture loss from the semipermeable container is within permissible limits.

Decision: Registration Board decided to approve registration of "Helisopt Ophthalmic Suspension" by M/s Helix Pharmaceuticals. Manufacturer shall place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

d. Exemption from onsite verification of stability data (Deferred cases)

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1850.	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.	Tigrelor 90mg tablet Each film-coated tablet contains: Ticagrelor...90mg (Platelet Aggregation Inhibitor) Innovator's specifications	Form- 5 Dy.No.931 Dated: 22-12-2014 Rs.50,000/- (17-12-2014) 2 x 10's; as per SRO	Brilinta 90 mg film-coated tablets of M/s AstraZeneca UK Limited (MHRA Approved) / Not applicable Last GMP inspection was conducted on 12-12-2017 and GMP certificate was issued on 15-12-2017.

STABILITY STUDY DATA			
Drug	Tigrelor 90mg tablet		
Name of Manufacturer	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-TG-201709061		
Description of Pack (Container closure system)	Alu- Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (month) Real Time: 0, 3, 6, 9, 12 (months)		
Batch No.	17PD064TICT05	17PD081TICT06	17PD089TICT07
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Nov-2017	Dec-2017	Dec-2017
Date of Initiation	29-01-2018	29-01-2018	30-01-2018
No. of Batches	04		
Date of Submission	16-08-2018 (27937)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
9.	CoA of API	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.

11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Firm has submitted 6 months accelerated and 12 months real time stability study data of four batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 02-07-2019 vide diary no. 10339

Administrative Portion

20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Apixa 2.5mg and 5mg (Apixaban) Tablets", which was presented in 289th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Pharmatec Pakistan (Private) Ltd, Karachi. Date of inspection: 30-04-2019 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
22.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted COAs of following working standards & impurity Standards : Ticagrelor working standard (B # WS201603001) Ticagrelor working standard (B # WTG01-170401) Impurity standards TG16 WRS (B# WTG05-170401) De-Ethoxyl of TG WRS (B# WTG06-170401)
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
24.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for evaluation of vendors.

<table>
<tr><td>25.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.</td></tr>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Ticagrelor 90mg Tablet”.</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>30-01-2018</td></tr>
</table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Trial No</td><td>Total no. of Tablets For stability testing</td><td>Tablets used for testing</td><td>Remaining Quantities of tablets</td></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>1800 Tablets</td><td>700 tablets</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 29-11-2017 to</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Ticagrelor.</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ticagrelor 90mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Nantong Chanyoo Pharmatech Co., Ltd. China. The storage conditions for real time stability data are 25±2ºC/60±5%RH.</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>36.</td><td>Drug-excipients compatibility studies.</td><td>The compatibility of Ticagrelor 900mg (API) and 40mg Sodium lauryl sulphate (Excipient) was studied by HPLC analytic techniques after storage of mixture under accelerated conditions. HPLC analysis of these mixtures has not shown any significant physical and</td></tr>
</table>

		chemical instability. Hence the study concludes that Ticagrelor and sodium lauryl sulphate are compatible.
37.	Record of comparative dissolution data.	The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Ticagrelor 90mg tablet and Brilinta 90mg tablet. The results suggest similarity factor (f2) > 50 and difference factor (f1) < 15 in all three media.
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Ticagrelor 90mg Tablet" from.

Sr. No.	Observations communicated	Response by the applicant
5.	Digital data logger record does not cover the duration of stability study data. Clarification is required.	Digital logger sheets which cover the duration stability study data.
6.	Justification is required for preparation of four batches for the purpose of carrying out stability studies.	The first batch exhibiting the batch number 17PD048TICT04, is the pre-formulation batch, the very initial batch developed at every step of formulation development, this supports in making decision. These steps include process feasibility studies, formulation optimization and manufacturing process.
7.	Audit trail reports of only one date are submitted. It is important to submit the audit trail reports at all time points of stability studies as well as comparative dissolution study.	Audit trail on the testing time point is submitted.
8.	Polymorphic formof Ticagrelor API is required to be submitted.	The firm has submitted that polymorphic form-II was used and further stated that same form of molecule is discussed in the patent of Astra Zeneca. The form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction.

Storage conditions under which stability studies were conducted are at 25ºC±2ºC/60%±5% RH.
Previous Decision: Deferred for submission of scientific justification for conducting API stability studies at storage conditions of 25ºC±2ºC/60%±5% RH.
Evaluation by PEC: The firm has submitted that internationally API stability studies are conducted at 25ºC±2 ºC/60%±5%RH because majority of API manufacturer supplies their product to international market. When we receive APIs, we keep them in controlled temperature i.e., 25ºC. When we manufacture our finished product with these APIs, we use to conduct stability studies of our products according to our stability Zone i.e., Zone IVA.

Previous Decision: Registration Board deferred the case for submission of valid GMP certificate of M/s Nantong Chanyoo, Jiangsu province, China, issued by relevant Provincial or state Regulatory authority since the Nantong Food and Drug Administration is not the relevant provincial regulatory authority (M-293).
Response of the firm: Firm has submitted copy of "License for Drug production" issued by the Jiangsu Food and Drug Administration in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., China with License number "S. 20160512" and valid upto 31-12-2020.
The above cited certificate has been verified from the following web link of National Medical Product Administration of China:
http://app1.sfda.gov.cn/datasearchcnda/face3/base.jsp?tableId=34&tableName=TABLE34&title=%D2%A9%C6%B7%C9%FA%B2%FA%C6%F3%D2%B5&bcId=152911762991938722993241728138 .

Deferred for following submissions (M-294):

- Submission of real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product as per the decision of 290th meeting of Registration Board since the firm has used API whose stability testing has not been done as per the conditions of Zone IV-A.
- Scientific justification for performance of drug excipient compatibility studies with only 1 excipient (i.e. Sodium lauryl sulphate).
- Status whether form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction by M/s Pharmatec or API manufacturer

Evaluation by PEC: The firm has submitted following:

- Stability study data of API as per Zone IV-A.
- Drug Excipient compatibility was conducted and assessed through HPLC. Binary mixtures of excipient and drug substance at a ratio 1:1 ratio in the solid state were prepared. Results showed no interference/degradant was detected with any of the excipient used.
- Crystalline Form-II of Ticagrelor is confirmed by melting points & X-Ray diffraction as per DMF of API manufacturer.

Decision: Registration Board decided to approve registration of Tigrelor 90mg Tablet with Innovator's specifications by M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
1851.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Tofacit 5mg Tablet Each Film Coated tablet Contains: Tofacitinib (as citrate) ……5mg Selective immunosuppressants ATC code: L04AA29	Form-5 Dy. No. 34109: 15.10.2018 PKR 20,000/-: 04.08.2018 As per SRO	XELJANZ 5 mg film-coated tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

Case history:

Decision of 290th meeting of Registration Board:

Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies and generic / me-too status which were adopted by the Registration Board in its 275th meeting.

Now the firm has submitted the reference and generic evidence which is as under:

Reference status "XELJANZ 5 mg film-coated tablets (Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium"

Generic/me-too status " Xeljanz Film Coated Tablet 5mg of M/s Pfizer"

Decision of 293rd meeting of Registration Board:

Deferred for further deliberation regarding stability data.

The stability data of 3 batches have been submitted by the firm

STABILITY STUDY DATA

Manufacturer of API	Kaifeng Pharmaceutical (Grp)Co. Ltd. No. 1 Yunan Street Kaifeng
API Lot No.	KFX171203
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH

Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	11-2018	12-2018	12-2018
Date of Initiation	14-11-2018	20-12-2018	20-12-2018
Date of submission	4648 (16-03-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number 783242202418.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu‘s LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment,

		personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number 783242202418.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 70 Tablets TF-02: 98 Tablets TF-03: 108 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated stability studies & long term stability studies reports of three batches of API.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of their product against the Xeljanz Tablet. The drugs show more than 85% release in 15 minutes at all media.

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Submit protocols for stability studies	Firm has submitted protocols for stability studies.
You have provided dissolution specifications as NLT 75% in 15 minutes without specifying the value of "Q".	Firm has submitted revised dissolution specifications with acceptance criteria NLT 75%(Q) after 15 minutes
Submit stability study data of API	Firm has submitted the stability study data of API for three batches.

Decision: Registration Board decided to approve registration of Tofacit 5mg Tablet (Tofacitinib, Selective immunosuppressants, ATC code: L04AA29) with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case no. 05: Registration applications of locally manufacturing drugs (human) submitted on CTD format

1852.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18270 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..12.5mg Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Synjardy 12.5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: M/s. Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity

		factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1853.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18269 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ºC ±2ºC & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1854.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18268 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 500mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study

		data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1855.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20014 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------

	The status in reference regulatory authorities	Synjardy 5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ºC ±2ºC & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.

	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1856.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20013 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical

		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ºC ±2ºC & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1857.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18267 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	----------
	The status in reference regulatory authorities	Synjardy 5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ºC ±2ºC & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC &

		75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India		
API Lot No.	Empagliflozin: Metformin hydrochloride:		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Strengths applied	Batch No	Batch size	Manufacturing date
EMPOLI Plus 12.5mg + 1000mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 1666 Tablets 1666 Tablets	November 2018 November 2018 November 2018
EMPOLI Plus 12.5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 12.5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 5mg + 1000mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	January 2019 January 2019 January 2019
EMPOLI Plus 5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	January 2019 January 2019 January 2019

EMPOLI Plus 5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	November 2018 November 2018 November 2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years TEFOD *(Tenofovir Alafenamide)* 25mg Tablets on 28th January, 2019 by following panel: 1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board 2. Mr. Aslam Shah, Member Registration Board. 3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. Metformin hydrochloride: The firm has submitted copy of GMP certificate for M/s Wanbury Limited, Andhra Pradesh, India. The certificate is valid till 05-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of invoice for the import of Empagliflozin (1kg) attested by AD (I&E) Karachi office dated 08-11-2018. Metformin hydrochloride: Firm has submitted copy of invoice for the import of metformin hydrochloride (1.5kg) attested by AD (I&E) Karachi office dated 25-05-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC

Shortcomings communicated	Response by the firm
Though you have submitted summary of batch analyses release results of the FPP manufacturer for relevant batches in quality overall summary, however it is not provided in relevant section of module 3	The firm has provided data of relevant section of Module 3.
Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) (Empagliflozin and metformin hydrochloride) shall be submitted as per section 3.2.S.4-Control of drug substance	The firm has submitted analytical method verification studies for both drug substances.

How it is possible even in the presence of stress conditions, no degradation/impurities were observed in specificity parameter of analytical validation of finished product. Please justify your findings.	The firm has submitted that selectivity of method can be determined by following two methods • Spiking of impurities • Forced Degradation We performed both methods and no degradation has been observed due to high stability of these molecules.
The justification of specification(s) for non-pharmacopeial products must be provided.	The firm has submitted that we have developed in-house justification for inclusion of tests non-pharmacopoeial.
Details of reference standards needs to be submitted since details of metformin impurity A and metformin impurity F are submitted without mentioning API reference standard. In case of Empagliflozin, working standard of API has been procured. Justify the quantity of working standard procured will it be sufficient for complete test and analysis.	The firm has submitted that assay of Metformin hydrochloride performed by titrimetric method hence working standard not required. While for testing of finished product, reference standard is used to standardize the working standard. The firm has submitted justification for quantity of working standard procured for test and analysis. Amount of working standard procured is 125mg. 125mg is used for analysis of API. 125mg is used for standardization of in-house standard. 10mg working standard required for single analysis of finished product. No. of testing per strength is 6mg (60mg consumed). Total no. of testing per 6 strength is 36mg (360mg consumed).
Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	The firm has performed pharmaceutical equivalence of their test formulations with different strengths of Synjardy as below: • Synjardy 12.5/1000mg Tablets (Boehringer Ingelheim, Batch # 644963) • Synjardy 12.5/850mg Tablets (Boehringer Ingelheim, Batch # 544531) • Synjardy 12.5/500mg Tablets (Boehringer Ingelheim, Batch # 856310) • Synjardy 5/500mg Tablets (Boehringer Ingelheim, Batch # 856327) • Synjardy 5/850mg Tablets (Boehringer Ingelheim, Batch # 644574) • Synjardy 5/1000mg Tablets (Boehringer Ingelheim, Batch # 644648)
Though you have submitted brief summary of CDP with innovator in module 2, however the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed in relevant portion of module 3.	The firm has submitted performance of comparative dissolution test of their test formulations against innovator formulations in 3 different pH media i.e., 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8 for relevant section of module 3. The results show comparable dissolution with innovator's product

Decision: Registration Board decided to defer the cases for justification of using Titrimetric method alongwith performance of potentiometric end point for analysis of metformin API.

1858.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28418 : 27-12-2019
	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..50mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 50mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)
	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1859.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28419: 27-12-2019
	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 75mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..75mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 75mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)

	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA

Manufacturer of API	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
API Lot No.	6TDL 0110318
Description of Pack (Container closure system)	Alu-Alu Blister 1×10's

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
	Batch No.	Batch size	Manufacturing date
D-PAIN 50MG TABLET	T-001 T-002 T-003	1500 Tablets	09-2018
D-PAIN 75MG TABLET	T-001 T-002 T-003	1000 tablets	09-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#JX170001) for M/s Symed Labs Limited, India issued by Drug Control Administration, Government of Telangana, India. It was valid till 24-04-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Dissolution conditions of innovator as per Biopharmaceutics Review:
Apparatus: Type I (Basket apparatus)
Spindle rotation: 75 RPM
Medium: 0.1 M HCl
Medium volume: 900ml
Time: 45 min
Acceptance criteria: NLT 80% (Q) of the labelled amount of Tapentadol (as HCl) dissolved in 45 min

Sr. No.	Observations communicated	Response by the firm

9.	Submit Quality Overall Summary (QOS) needs to be submitted as per 293rd meeting of Registration Board.	The firm has submitted summarised information of drug substance and drug product as per 293rd meeting of Registration Board
10.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
11.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	The firm has submitted copy of GMP certificate however it is expired now.
12.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
13.	Summary of batch analyses release results of the drug product manufacturer for relevant batch needs to be submitted as per 2.3.S.4.4 (b).	Submitted
14.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Tapento IR 75mg tablet. Unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., 50mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.
15.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	Submitted.
16.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted data of relevant modules.

Decision: Registration Board decided as follows:

- **To defer registration application of D-Pain 50mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **To approve registration of D-Pain 75mg tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.**

1860.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4211: 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020
	The proposed proprietary name / brand name	Asprala 81mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated delayed release tablet contains: Aspirin……..81mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Film coated delayed release Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent and proton pump inhibitor
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablets 81mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 81mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Andra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Aspirin: The Firm has submitted 6months accelerated (40°C ± 2°C/75%± 5% RH) and 60months real time (30°C ± 2 °C/60%± 5% RH) stability study data of 3 batches.

		Omeprazole: The Firm has submitted 6months accelerated (40ºC ± 2ºC/75%± 5% RH) and 48months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1861.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4210 : 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020
	The proposed proprietary name / brand name	Asprala 325mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin……..325mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent (B01AC06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	YOSPRALA Tablets 325mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 325mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Aspirin:** The Firm has submitted 6months accelerated (40ºC ± 2 ºC/75%± 5% RH) and 60months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches. **Omeprazole**: The Firm has submitted 6months accelerated (40ºC ± 2 ºC/75%± 5% RH) and 48months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA	
Manufacturer of API	**Aspirin:** M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China **Omeprazole:** M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India
API Lot No.	**Aspirin:** 171315 **Omeprazole:** OME/E-222/16

Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	Batch size	Manufacturing date
ASPRALA 81MG/40MG TABLET	TT-001 TT-002 TT-003	13000 Tablets 13000 Tablets 13000 Tablets	06-2018 06-2018 06-2018
ASPRALA 325MG/40MG TABLET	TT-001 TT-002 TT-003	1500 Tablets 1500 Tablets 1500 Tablets	09-2019 09-2019 09-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Aspirin:** The firm has submitted copy of GMP certificate for M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China issued by Shangdong Food and Drug Administration. It is valid till 18-10-2022. **Omeprazole:** The firm has submitted copy of GMP certificate for M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India issued by Government of Telangana, Drugs Control administration. It was valid till 31-03-2017.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** Firm has submitted copy of commercial invoice specifying import of 5Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office dated 11-06-2018. **Omeprazole:** Firm has submitted copy of commercial invoice specifying import of 100Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office dated 13-05-2016.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Sr. No.	Observations communicated	Response by the firm
7.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Evidence of import of both APIs attested by AD (I&E), Islamabad is submitted
8.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	Valid GMP certificate for omeprazole is yet to be submitted.
9.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
10.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Yosprala 325mg/40mg tablet. But unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., Yosprala 81mg/40mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.
11.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	The firm has submitted analytical method validation studies.
12.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted details of drug substance and drug product as per 293rd meeting of Registration Board.

Decision: Registration Board decided as follows:

- **to defer registration application of Asprala 81mg/40mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **to approve registration of Asprala 325mg/40mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.**

Item No. : Agenda of Evaluator AD PEC-I

Item No. I: Registration Applications for Local Manufacturing of (Human) Drugs
a. New Cases

2105.	Name and address of manufacturer / Applicant	M/s Skim Pharmaceuticals 10/B value addition city Faisalabad
	Brand Name +Dosage Form + Strength	SKIFENAC Diclofenac Sodium 50mg sustain coated pellets
	Diary No. Date of R& I & fee	Each capsule contains: Diclofenac sodium sustained release pellets….50mg Source of Pellets: M/s Vision Pharmaceutical Islamabad

	Composition	Dy. No. 20075 dated 04-06-2018 Rs20,000/-Dated 04-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20,s capsule in Alu/PVC Blister & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac sodium 25mg & 50mg) gastro resistant **Tablet** by M/s Daxcel Pharma, MHRA Approved.
	Me-too Status	Lifdik 50mg capsule by M/s Goodmann, Reg No. 52586
	GMP Status	DML No. 000830 issue dated 03-12-2015 Panel recommended additional sections including Capsule (general) dated 19-01-2018
	Remarks of the Evaluator-I	The firm initially applied for Sustained Release Capsule and then it was revised as Enteric coated Capsule as per reference product and submitted fee Rs. 5,000/- vide challan number 0300788 dated 13/04/2020.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2106.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 1.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38171 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…….1.5mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's, Rs. 1000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 1.5mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. No. 079270
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2107.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 9mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38174 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…9mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5D
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 4000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.

	Me-too Status	Could not be confirmed
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	• The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system. • Me too status could not be confirmed.
	Decision: Deferred for; • **Clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2108.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38173 dated 20-11-2018 Rs.20,000/- Dated
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…6mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 2700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Avega 6mg Tablets by M/s Biogen Pharma, Reg No. 080370
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2109.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 3mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38172 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone……3mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 1700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets 1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 3mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. no. 079271

	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2110.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 50mg Tablets
	Diary No. Date of R& I & fee	Form-5D Dy.No 37929 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate……50mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D
	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 12,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	The firm has claimed In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). 06 month submit stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	
2111.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 100mg Tablets
	Diary No. Date of R& I & fee	Form-5D Dy.No 37928 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate……100mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D
	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 20,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	Stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	

2112.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 50mg/200mcg Tablets
	Diary No. Date of R& I & fee	Dy.No 38150 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 50 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Prostol Tablets by M/s Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore, Reg. No. 026839
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following; Each delayed release tablet contains: Diclofenac sodium…..50mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2113.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 75mg/200mcg Tablets
	Diary No. Date of R& I & fee	Dy.No 38151 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…..……75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 75 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Arsofin Tablets by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Reg. no. 48013
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following;

		Each delayed release tablet contains: Diclofenac sodium…..75mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…….50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2114.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Zipdone 40mg Capsule
	Diary No. Date of R& I & fee	Dy.No 38145 dated 19-11-2018 Rs.12,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….40mg
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 40mg capsule of M/s Nabiqasim Industries (Reg.#055651)
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The reference product contains Ziprasidone hydrochloride monohydtrate while the applied formulaiton contains Ziprasidone hydrochloride, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Ziprasidone Hydrochloride" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2115.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Applicant/Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Mol 1g/100ml Infusion (solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 37901 dated 16-11-2018 Rs.50,000/-
	Composition	Each 100ml Contains: Paracetamol…….1g
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paracetamol 10mg/ml Solution for Infusion (50ml vial, 100ml vial) by M/s Accord UK ltd, MHRA approved

	Me-too Status	Provas Infusion 10mg/ml by M/s Sami Pharma, Reg. No. 53223
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2116.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ferolas 100mg/5ml Injection
	Diary No. Date of R& I & fee	Dy.No 37900 dated 16-11-2018 Rs.50,000/-
	Composition	Each 5ml (ampoule) Contains: Iron as Iron Sucrose……100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2117.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ton 8mg/4ml Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 37894 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018

	Composition	Each 4ml ampoule Contains: Ondansetron……8mg
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ondansetron 2 mg/ml (4mg/2ml & 8mg/4ml) Solution for Injection by M/s Hameln pharmaceuticals, MHRA Approved
	Me-too Status	Doston 8mg/4ml Injection by M/s Vision Pharmaceuticals, Kahuta Road, Islamabad. Reg. No. 081892
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2118.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Lac 30mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37893 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Ampoule (1ml) Contains: Ketorolac Tromethamine……..30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Toradol Injection 30mg/ampoule of 1ml by M/s Atnahs Pharma, UK (MHRA Approved)
	Me-too Status	Tromit Injection by M/s harm (Reg.# 049958)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.

	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2119.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Bufin 10mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37891 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (1ml) Contains: Nalbuphine HCl……10mg
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved.
	Me-too Status	Nalburax Injection by M/s Mediceena Pharma (Pvt) Ltd, Reg. No. 28830
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2120.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Penzol 40mg/Vial Injection (Lyophilized powder for solution for injection)
	Diary No. Date of R& I & fee	Dy.No 37892 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Pantoprazole as Sodium ……..40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	**PROTONIX IV** 40mg Powder (freeze dried) for Solution for Injection by M/s Wyeth Pharms, USFDA Approved.
	Me-too Status	Zonpep Injection 40mg IV by M/s Aulton Pharmaceuticals, Reg. No.
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin

		Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2121.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-D3 5mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37895 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (ml) Contains: Cholecalciferol……..5mg (Eq. to approx. 200,000IU)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too Status	G-Cal 5mg Injection by M/s Glitz Pharmaceuticals, Reg. No. 66362
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2122.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Zole 40mg/Vial IV Infusion (Lyophilized Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37896 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Omeprazole as Sodium…..…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.

	Regulatory Authorities	
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2123.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 1g Injection (Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37899 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Vancomycin as HCl…….1000mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	Vancocin Inection 1000mg of Eli Lilly Pakistan, Reg. No. 21081
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2124.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 500mg Injection

	Diary No. Date of R& I & fee	Dy.No 37898 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Vancomycin as Hcl….500mg (powder for injection)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	VANCIN I.M / I.V INJECTION 500MG by M/s CENTURY PHARMACEUTICAL (PVT) LTD, Reg. No. 22673
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2125.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Cycline 50mg Injection (Powder for solution)
	Diary No. Date of R& I & fee	Dy.No 37897 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Tigecycline……..50mg
	Pharmacological Group	Tetracycline derived antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tigecycline 50 mg lyophilized cake or powder for solution for infusion by M/s Mylan (MHRA Approved)
	Me-too Status	Tygacil Injection 50mg by M/s Wyeth (Reg#045642)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide

		letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2126.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ronic 3mg/3ml Injection
	Diary No. Date of R& I & fee	Dy.No 37903 dated 16-11-2018 Rs.50,000/-
	Composition	Each 3ml Contains: Ibandronic Acid…….3mg
	Pharmacological Group	Bone resorption inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ibandronate sodium 3mg/3ml vial by M/s Sun Pharm, USFDA Approved.
	Me-too Status	Ibro injection 3mg/3ml by M/s Regal Pharmaceuticals (Reg#082004)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2127.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Esom IV 40mg Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Dy.No 37902 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections:

		Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2128.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 4mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37921 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….4mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too Status	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2129.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 8mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37926 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam……..8mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too Status	Recam Tablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2130.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37922 dated 16-11-2018 Rs.20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008473 dated 24/01/2020.
	Decision: Deferred for; • **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
2131.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37925 dated 16-11-2018 Rs.20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	Anti-depressants
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008474 dated 24/01/2020.
	Decision: Deferred for; • **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
2132.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Uniterf Fort 250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37923 dated 16-11-2018 Rs.20,000/-
	Composition	Each Tablet Contains: Terbinafine as HCL……250mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s NOVARTIS PHARMACEUTICALS UK LIMITED, MHRA Approved.
	Me-too Status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	

	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2133.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Dianil 2mg Capsule
	Diary No. Date of R& I & fee	Dy.No 37924 dated 16-11-2018 Rs.20,000/-
	Composition	Each Capsule Contains: Loperamide Hydrochloride…2mg
	Pharmacological Group	***Antidiarrheals***
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6×10, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loperamide Capsules 2 mg by M/s Galpharm Healthcare Limited, MHRA Approved.
	Me-too Status	LOPAMIDE 2mg CA by M/s Medicaids, Reg. No. 11240
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2134.	Name and address of manufacturer / Applicant	M/s Ciba Pharmaceutical private limitd, plot no. A-371, Nooriabad site industrial Area, Super highway Karachi.
	Brand Name +Dosage Form + Strength	LINO 500mg capsule
	Diary No. Date of R& I & fee	Dy.No.35276 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Lincomycin……..500mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2,6's×2, 5's×10, 10's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too Status	Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898
	GMP Status	According to the Last inspection report dated 07/02/2017, the firm is strictly following the GMP practice.
	Remarks of the Evaluator-I	The applied product is present in USP as well as BP. The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. Provide the proof of availability of Raman spectrometer if you want to claim USP specifications for the applied product. Provide evidence of approval of the applied product is Reference Regulatory Authorities approved by 275th meeting of Registration Board as the product is discontinued by USFDA and ANSM France.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2135.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16256 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…1gm
	Pharmacological Group	Cephalosporin

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82749
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2136.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16255 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…500gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82750
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2137.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 1gm IV Injection
	Diary No. Date of R& I & fee	Dy.No 16566 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm with L-Arginine Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
2138.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 500mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 16565 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride with L-Arginine 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
2139.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 250mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16247 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference	Ceftriaxone (250mg & 1gm) powder for solution for

	Regulatory Authorities	injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 250mg IM by M/s Caliph pharmaceuticals (Pvt.) Ltd, Reg. no. 82556
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2140.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 250mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16254 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…250gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA MHRA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2141.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16250 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma:

		The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2142.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16249 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2143.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 1g IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16251 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the

		manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2144.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 100mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16257 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…100mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2145.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 200mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16258 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…200mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30 ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2146.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan

		Manufactured By: M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 16259 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Capsule Contains: Cefixime as Trihydrate….400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2147.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mg
	Pharmacological Group	
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2148.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection

	Diary No. Date of R& I & fee	Dy.No 16253 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…1gm Cefoperazone as Sodium…1gm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015 273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2149.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations

	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2150.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi
	Brand Name +Dosage Form + Strength	Diraximin 200mg Tab
	Diary No. Date of R& I & fee	Dy.No 266 dated 09/11/2016 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each Film Coated Tablet Contains: Rifaximin……200mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 200mg film-coated tablets, for oral use. **USFDA** approved
	Me-too Status	Nimixa 200mg Tablet film-coated. Reg. No. 70734
	GMP Status	The panel dated 04-10-2019 recommends for renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2151.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	NS+20K Infusion 100ml
	Diary No. Date of R& I & fee	Dy.No 71 dated 10/09/2013 Rs.50,000 Dated 10-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each ml contains: Sodium chloride……..9mg Potassium chloride…..150mg
	Pharmacological Group	Electrolytes
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml vial(as per SRO)
	Approval Status of Product in Reference Regulatory Authorities	Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion – BP by M/s Baxter healthcare, MHRA Approved. (strength is not same)
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	The applied product does not contain the same strength of potassium chloride as the product contains approved by reference regulatory authorities (RRAs). Provide evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revise the formulation along with the applicable fee. evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for; • **Evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2152.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Acbenzo 4% w/w Cream
	Diary No. Date of R& I & fee	Dy.No 1399 dated 13/01/2017 Rs.20,000 Dated 05-01-2017 **Duplicate file** The file is received from R-I Section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 100g cream contains: Benzoyl Peroxide….4g
	Pharmacological Group	Anti infective
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Brevoxyl 4% Cream by M/s GSK consumer healthcare, MHRA Approved.
	Me-too Status	Prayzid Cream 4% cream by M/s Pray Pharma, Reg. No. 72415
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2153.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colonclean Syrup
	Diary No. Date of R& I & fee	Dy.No 69 dated 10/09/2013 Rs.50,000 Dated 04-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 5ml contains: Sodium potassium monobasic….2.4g Potassium dibasic…….0.9g
	Pharmacological Group	Purgative
	Type of Form	Form-5D
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for; • **Evidence of approval of the same formulation in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2154.	Name and address of manufacturer / Applicant	**Manufacturer:** M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore

		Applicant: M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd , Lahore
	Brand Name +Dosage Form + Strength	Cewel Dry suspension 100mg/5ml
	Diary No. Date of R& I & fee	Dy.No 5800 dated 05/07/2010 Rs.8,000 Dated 03-07-2010 Differential fee 42,000/- dated 22/01/2015 **Duplicate file** The application is received from R-II section vide letter no. F.1-11/2019-Reg-II dated 24/12/2019.
	Composition	Each 5ml reconstituted suspension contains: Cefixime Trihydrate equivalent to Cefixime…100mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Harmann Pharma: **Decision of 272st Meeting of CLB:** I- Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections. a- Sterile Section-I (General Injection) b- Sterile Section-III (Hormonal Injection) II- Regularize the layout plan of Hormonal Section, as per recommendations of the panel in the reort dated 13-06-2019 & 08-10-2019. Synchro Pharma: Inspection report dated 30/06/2020. "it was observed that firm had rectified most of the shortcomings and for remaining shortcomings fir was advised to submit CAPA within stipulated time and re-inspection will be conducted accordingly".
	Remarks of the Evaluator.	Copy of agreement is attached The applicant has stated that there are no products being manufactured on contract. M/s Harmann Pharma has 7 approved sections.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder suspension cephalosporin section" for applied formulation.	
2155.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nystanil oral solution 100,000 units/ml
	Diary No. Date of R& I & fee	Dy.No 9908 dated 25/07/2017 Rs.20,000 **Duplicate dossier** The application is received from R-I section vide letter no. F.1-2/2019-Reg-I dated 01/01/2020.
	Composition	Each ml contains: Nystatin……100,000 units
	Pharmacological Group	antimycotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nystatin Oral Suspension BP by M/s Sandoz ltd, MHRA approved.
	Me-too Status	Nystrin Suspension 100,000/- per ml by M/s Harmann Pharma, Reg. No. 28119

	GMP Status	09-10-2018 Routine GMP Inspection "overall GMP compliance level is rated as good." Liquid syrup section is available.
	Remarks of the Evaluator.	• The applied product is Oral Solution while the approved product is reference country is Oral Suspension, provide the evidence of approval in reference regulatory authorities as approved by Registration Board in 275th meeting or otherwise submit revised formulation as per reference product along with the submission of applicable fee. • The firm has revised formulation the formulation from Oral Solution to Oral Suspension as per the reference product and submitted fee (Rs. 5,000/- challan number 1976772 dated 30/07/2020 + Rs. 15,000/- challan number 2034651 dated 09/09/2020).
	Decision: Approved with the following details; **Brand name:** **Nystanil oral suspension 100,000 units/ml** **Label Claim:** **Each ml contains:** **Nystatin……100,000 units** **Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.**	
2156.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra Injection 500mg/5ml
	Diary No. Date of R& I & fee	Dy.No 14122 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each 5ml contains: Levetiracetam…500mg
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 325/- per ampoule
	Approval Status of Product in Reference Regulatory Authorities	KEPPRA 500mg/5ml Injection of USFDA approved
	Me-too Status	Lumark Injection M/s Searle Pak
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Injectable section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2157.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra 100mg/ml Oral solution
	Diary No. Date of R& I & fee	Dy.No 14123 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each ml contains: Levetiracetam…100mg
	Pharmacological Group	antiepileptic

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs 432/- per 60ml, Rs. 720/- per 120ml
	Approval Status of Product in Reference Regulatory Authorities	LEVETIRACETAM (Levetiracetam100mg/ml) solution; oral By M/s TARO. USFDA Approved.
	Me-too Status	Levotam Oral solution 100mg/ml By M/s Platinum, Karachi. (Reg.# 070837)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Oral liquid section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2158.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Oxepin Capsules 3/25mg
	Diary No. Date of R& I & fee	Dy.No 14124 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each capsule contains: Olanzapine……..3mg Fluoxetine as HCl…….25mg
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 20/- per capsule
	Approval Status of Product in Reference Regulatory Authorities	Symbyax 3mg/25 mg Capsules by Ms/ Eli Lilly, USA (USFDA approved).
	Me-too Status	Olanco Capsules by Genome Pharma. (Reg. # 079388)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Capsule section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2159.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore. **Manufacturer:** M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Esomark 40mg Infusion Lyophilized powder for infusion
	Diary No. Date of R& I & fee	Dy.No 3083 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Esomeprazole as Sodium…..400mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)

	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.
	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2160.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore. **Manufacturer:** M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Biomep 40mg Infusion Lyophilized powder for solution
	Diary No. Date of R& I & fee	Dy.No 3084 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.
	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2161.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Phlocin Injection
	Diary No. Date of R& I & fee	Dy.No 485 dated 21-03-2014 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II.
	Composition	Each 4ml ampoule contains: Phloroglucinol hydrate……40mg

		Trimethylphloroglucinol…..0.04mg
	Pharmacological Group	Antispasmodic.
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too Status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP Status	GMP certificate issued on 10/12/2018 on the basis of inspection conducted on 08/11/2018. Liquid injectable section available
	Remarks of the Evaluator-I	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2162.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Florlina Plus powder
	Diary No. Date of R& I & fee	Dy.No 12 dated 01-07-2015 Rs.20,000 Dated 30-06-2015 **Duplicate file**
	Composition	Each 100g contains: Neomycin Sulphate……15gm Florfenicol……..10gm Oxytetracycline Hcl……..30gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	100gm, 200gm 500gm, 1kg, price decontrolled
	Me-too Status	NEOXFLOR ORAL POWDER (150mg, 100mg 300mm per gram) by M/s Baariq Pharma, Reg. No. 088638
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Deferred for updated status of GMP from QA & LT division.	
2163.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Enflox-c plus liquid
	Diary No. Date of R& I & fee	Dy. No 13 dated 01-07-2015 Rs.20,000 Dated 30-06-2015 **Duplicate file**
	Composition	Each 100ml contains: Enrofloxacin……..…10mg Cloistin sulphate…….100mg Amantadine HCl…..…300gm
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished Product Specification	Inhouse
	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Evidence of GMP is required.
	Remarks of the Evaluator.	
	Decision: Deferred for following: **Updated status of GMP from QA & LT division.** **Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name & name of firm.**	
2164.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Colate powder for solution for injection

	Diary No. Date of R& I & fee	Dy.No 39066 dated 29-11-2018 Rs.20,000 Dated 27-11-2018 (Duplicate file)
	Composition	Each vial contains; Colistimethate sodium…….1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Date of inspection 10/04/2019, acceptable level of cGMP compliance
	Remarks of the Evaluator-I	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2165.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Janumet tablet
	Diary No. Date of R& I & fee	Dy.No 28 dated 01-07-2014 Rs.20,000 Dated 01-07-2014 **Duplicate file**
	Composition	Each tablet contains: Sitagliptin……..50mg Metformin HCl……..500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 1,500/- per pack of 2×7's
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	The firm has submitted the correct composition as per the reference product given in the following without submission of any fee. Each film coated tablet contains: Sitagliptin as phosphate monohydrate……..50mg Metformin HCl…….500mg
	Remarks of the Evaluator.	
	Decision: Deferred for submission of requisite fee for revision of formulation as per reference product.	
2166.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Relspasm Injection 4mg/2ml
	Diary No. Date of R& I & fee	Dy.No 749 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(02/06/2011)+12,000(14/01/2015) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each ml contains: Thiocolchicooside……2mg

	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis (ANSM France)
	Me-too Status	Myolax 2mg Injection (4mg/2ml ampoule) by M/s Saffron, Reg. no. 60355
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019. Liquid injectable section is available.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2167.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Derams Injection 500mg IV Powder for solution
	Diary No. Date of R& I & fee	Dy.No 748 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(03/06/2011)+12,000(16/12/2014) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each vial contains: Thiopental sodium…500mg (as a mixture of Thiopental sodium and sodium carbonate)
	Pharmacological Group	Genera anesthetic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Thiopental Sodium 500mg Powder for Solution for Injection by M/s Kyova kirin ltd, MHRA Approved.
	Me-too Status	M-Pentone 500mg Injection by M/s Mediate, Reg. No. 61946
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019. Dry powder injectable section is available.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification of method of manufacturing of the applied product whether via lyophilization or dry powder filling alongwith reference / innovator's product manufacturing method.	
2168.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunate injection 250mg Powder for injection
	Diary No. Date of R& I & fee	Dy.No 166 dated 03-11-2016 Rs.20,000 Dated 02-11-2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone as sodium succinate……250mg
	Pharmacological Group	Glucocorticoid-Minerolcorticoid
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference	Hydrocortisone as sodium succinate Injection-USFDA

	Regulatory Authorities	
	Me-too Status	Solu-cortef by Pfizer Pharma
	GMP Status	Date of inspection 11-02-2019, good level of GMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of required manufacturing facility/section approval from Licensing division.	
2169.	Name and address of manufacturer / Applicant	M/s Zakfas pharmaceutical pvt Ltd. 12-Km, bosan raod, multan.
	Brand Name +Dosage Form + Strength	Gen-One topical spray
	Diary No. Date of R& I & fee	y.No 546 dated 09-06-2016 Rs.50,000 Dated 09-06-2016
	Composition	Each ml contains: Gentamicin as sulphate…….0.57mg Betamethasone as valerate……0.284mg
	Pharmacological Group	Antibiotic/corticosteroid
	Type of Form	Form-5D
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Me-too Status	Could not be confirmed
	GMP Status	
	Remarks of the Evaluator.	Section approval letter. GMP inspection report International availability. Stability required.
	Decision: Deferred for following; • **Required manufacturing facility/section approval from Licensing Division.** • **Latest GMP inspection report.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2170.	Name and address of manufacturer / Applicant	M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Exelor 50mg tablet
	Diary No. Date of R& I & fee	Dy.No 10146 dated 26-07-2017 Rs.20,000 Dated 24-07-2017
	Composition	Each film coat tablet contains: Vildagliptin……..50mg
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GALVUS (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pvt Ltd. TGA approved
	Me-too Status	V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908)
	GMP Status	Inspection date, 27/12/2018, the firm is working in compliance to GMP standards.
	Remarks of the Evaluator-I	The firm has revised the formulation from Film Coated to Uncoated Tablet with submission of Rs. 5000/- challan no. 1938304 dated 08/12/2019 as per the reference product given in the following; Each Tablet contains: Vildagliptin……..50mg
	Decision: Approved with innovator's specifications	
2171.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Azocin 250mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 (slip no. **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……250mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 150/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269
	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2172.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Azocin 500mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……500mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 275/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269
	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2173.	Name and address of manufacturer / Applicant	**Applicant:** M/s Global Pharmaceuticals, Plot No. 204-205, Industrial Triangle, Kahuta road, Islamabad.

	Contract manufacturing	**Manufacturer:** M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Glonate Injection 250mg
	Diary No. Date of R& I & fee	Dy.No 166 dated 03/11/2016 Rs.20,000/- dated 02/11/2016 + Rs. 30,000/- 10/11/2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone sodium succinate…….250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Global Pharma: Inspection date 26/12/2018, panel recommended renewal of DML. Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	Clarification is required since the product approved in reference country contains "Hydrocortisone as sodium succinate 250" while the label claim of the applied product is "Hydrocortisone sodium succinate 250mg". Form 5 is submitted by the manufacturer while it should be submitted by the applicant. Detail of number of products being manufactured for M/s Global Pharmaceuticals is required. Provide number of approved sections of M/s Global Pharmaceuticals.
	Decision: Deferred for submission of the followings; • **Evidence of approval of applied formulation containing "Hydrocortisone sodium succinate 250mg" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Form 5 is submitted by the manufacturer while it should be submitted by the applicant.** • **Detail of number of products being manufactured for M/s Global Pharmaceuticals is required.** • **Provide number of approved sections of M/s Global Pharmaceuticals.**	
2174.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……1000mgs
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/1000 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53404
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

2175.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40987 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2176.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Demant 5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…5mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Torrent 5mg Film-coated Tablets by M/s Torrent Pharma (UK) Ltd, MHRA Approved.
	Me-too Status	Afdol 5mg Tablets by M/s AGP (R # 047166)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2177.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Demant 10mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41017 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…10mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Accord (5mg, 10mg, 15mg, 20mg) film-coated tablets by M/s Accord, MHRA Approved.
	Me-too Status	Afdol 10mg Tablets by M/s AGP (R # 044429)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2178.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals,

		Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 250mg
	Diary No. Date of R& I & fee	Dy. No. 41005 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….250mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote 250mg Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 250mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024464)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2179.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 500mg
	Diary No. Date of R& I & fee	Dy. No. 41006 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….500mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote (250mg, 500mg) Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 500mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024465)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2180.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 20mg
	Diary No. Date of R& I & fee	Dy. No. 40997 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……20mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 20mg tablet by M/s Getz Pharma, Reg. No. 33430
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovatpr's specifications.	
2181.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals,

		Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 40mg
	Diary No. Date of R& I & fee	Dy. No. 40998 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 40mg tablet by M/s Getz Pharma, Reg. No. 33431
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2182.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Omefit 40mg Capsules
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Omeprazole enteric coated pellets…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Losec Capsule (20mg, 40mg) by M/s Astra Zaneca (MHRA Approved)
	Me-too Status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	Source= Vision Pharma,
	Decision: Approved.	
2183.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 25mg
	Diary No. Date of R& I & fee	Dy. No. 40989 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

2184.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 12.5mg
	Diary No. Date of R& I & fee	Dy. No. 40990 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2185.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 10mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41004 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amlodipine and Olmesartan Medoxomil 10/20mg film coated tablet by M/s Torrent USFDA Approved.
	Me-too Status	Omsana-AM 10/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58559
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2186.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 5mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41003 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 5/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58557

	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2187.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metlipsy 800mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41000 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Piracetam 800mg film-coated tablet by M/s USB Pharma, MHRA approved
	Me-too Status	Nootropil Tablet 800mg by M/s GSK Reg. No. 82277
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2188.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mydin 10mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41024 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each tablet contains: Loratadine……..10mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Roletra 10 mg Tablets by M/s Ranbaxy (UK) Limited. MHRA approved
	Me-too Status	Senergy OD 10mg tablet by M/s Highnoon (Reg.#017672)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2189.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 20mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.…20mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 20mg tablet by M/s ' Highnoon Laboratories, Reg. no. 48371

	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2190.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 40mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.….40mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Aurora Tablets 40mg by M/s Ferozsons Laboratories, Reg. no. 54747
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2191.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Relaxer tablet 4mg
	Diary No. Date of R& I & fee	Dy. No. 41019 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each uncoated tablet contains: Thiocolchicoside ……4mg
	Pharmacological Group	Anti Parkinson, neuralgia
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	THIOCOLCHICOSIDE EG 4 mg, scored tablet. **ANSM France** approved
	Me-too Status	Myolax Tablets 4mg by M/s Reko Pharma Reg. No. 74170
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2192.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Konaz cream 2% w/w
	Diary No. Date of R& I & fee	Dy. No. 41023 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each gram contains: Ketoconazole… 20mg (2% w/w)
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Daktarin Gold 2% Cream by M/s McNeil Products Limited, MHRA Approved.
	Me-too Status	Bizrole Cream 2 % by M/s Searle IV Solutions (Pvt.) Ltd, Reg. No. 78620

	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
2193.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Binaf Cream 1% w/w
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Gram of cream contains: Terbinafine as HCl ……..10mg (1%)
	Pharmacological Group	Anti fungal
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Terbinafine HCl 1% cream by M/s Taro, USFDA Approved
	Me-too Status	Terbisan caream 1% by M/s Elko organization (PvT) ltd. Reg # 27076
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
2194.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metacid Oral Suspension
	Diary No. Date of R& I & fee	Dy. No. 41030 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each 5ml contains: Aluminium hydroxide…….215mg Magnesium hydroxide…….80mg Simethicone…….25mg
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be verified
	Me-too Status	Simecrol Suspension by M/s Hicon Pharmaceuticals (Reg.#041458)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

b. Deferred Cases (Local manufacturing) Human

2195.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi. (8 sections)

	Brand Name +Dosage Form + Strength	MAXI Eye Drops (Opthalmic Solution)
	Diary No. Date of R& I & fee	Dy.No.35273 dated 12/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Moxifloxacin as HCl…….5mg
	Pharmacological Group	Anti-infective/Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MOXIVIG 0.5%w/v eye drops, solution by M/s Novartis Pharmaceuticals UK Limited, MHRA Approved.
	Me-too Status	Ocumox-D Eye Drops by M/s Remington Pharmaceutical Industries, Reg No. 67888
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution and submitted Rs. 5000/- vide Callan number 1909480 dated 29/11/2019. The applicant has 08 sections. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035976 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Moxifloxacin as HCl…….5mg (Opthalmic solution) **Decision: Approved.**	
2196.	**deleted**	
2197.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	KATS sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35269 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Ketorolac Trimethamine……5mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	MFG
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketorolac trometamol 0.5% w/v eye drops, solution by M/s Brown & Burk UK Ltd,MHRA Approved.
	Me-too Status	Ketro 0.5% Eye Drops by Ms/ Vega Pharmaceuticals (Pvt) Ltd, Reg No. 54030
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has claimed In-House manufacturing specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The firm has revised the formulation of the applied product from ophthalmic suspension to ophthalmic

		solution and submitted Rs. 5000/- vide challan number 1909484 dated 29/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035977 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Ketorolac Tromethamine……5mg (Opthalmic solution) **Decision: Approved with innovator's specifications.**	
2198.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	PATLERG sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35270 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml contains: Olopatadine as HCl……..1mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Olopatadine 1 mg/ml Eye drops, Solution by M/s Brown & Burk UK Ltd, MHRA Approved.
	Me-too Status	Zolopat 0.5% eye drops by Ms/ Remington Pharmaceutical Industries**,** Reg. No. 065991
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909483 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035978 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..1mg (Opthalmic solution) **Decision: Approved.**	
2199.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	PATLERG FORTE Sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35271 dated 24/10/2018 PKR 50,000/-

	Composition	Each ml of suspension contains: Olopatadine as HCl……..2mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	OLOPATADINE HYDROCHLORIDE 0.2% opthalmic solution by M/s CIPLA, USFDA Approved.
	Me-too Status	Plop Forte Ophthalmic solution 2mg/ml by M/s Genix Pharma, Reg. No. 73680
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909482 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035979 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..2mg (Opthalmic solution) **Decision: Approved.**	
2200.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Omezole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40951 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial vontains: Omeprazole as Sodium…40mg (Lyophilized powder)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:**	

	The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2201.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Lorno 8mg for Injection IV/IM
	Diary No. Date of R& I & fee	Dy. No. 43539 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial contains: Lornoxicam……8mg (Lyopilized powder)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too Status	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for following: c. Confirmation whether application is by lyophilization process or powder filling. d. Registration status of M/s Biolab for same formulation. **Submission of the firm:** a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2202.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Esozole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40952 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg (Lyophilized powder of Esomeprazole sodium)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2203.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awablock 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole……40mg"
	Diary No. Date of R& I & fee	Dy. No 11728 dated 30-03-2018 Rs.50,000/- Dated 29-03-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi, (Reg#050651)
	GMP status	Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. The firm has applied for Esomeprazole 40mg while reference product contains Esomeprazole as sodium 40mg. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2204.	Name and address of manufacturer / Applicant	Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad Manufactured by

		Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	EPI 40mg Injection
	Composition	Each vial contain: Esomeprazole (as Sodium).....40mg
	Diary No. Date of R& I & fee	Dy. No. 5781 Date:29-08-2016 Rs. 50,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Nexium I.V. 40mg of (MHRA approved)
	Me-too status (with strength and dosage form)	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance
	Previous Remarks of the Evaluator [IV]	Contract agreement attached Number of already registred contract manufactured products: Nil
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products **(M-282)**
	Evaluation by PEC	Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision of 295th meeting: Registration Board deferred the case for confirmation of dry powder vial filling facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2205.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winlor 8mg Injection
	Composition	Each Vial Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 1153 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5

	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved
	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for following: • confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise. • DML status of M/s Alen **Submission by the firm:** a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic (Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. c. The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for following: **Confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.** **Confirmation of DML status of M/s Alen Pharmaceuticals pvt. Ltd, Risalpur.**	
2206.	**Name and address of manufacturer / Applicant**	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	BIMEP 40MG INJECTION IV
	Composition	Each vial contains: Omeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19491, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.

	Evaluation by PEC	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2207.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	NULOC 40MG INJECTION IV
	Composition	Each vial contains: Esomeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19492, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Nexium IV 40mg powder for solution for injection of AstraZeneca, UK (MHRA)
	Me-too status	Somezol Injection of Bosch, Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Firm's response	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2208.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winrose Injection 100mg/5ml
	Composition	Each ampoule contains: Iron sucrose…100mg
	Diary No. Date of R & I & fee	Dy. No. 1152 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020.

		Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• Revise the label claim and salt from in line with the reference product along with submission of applicable fee. • The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
2209.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zolid 600mg/300ml Infusion
	Composition	Each Vial Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 1151 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	D Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
2210.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Locrim 400mg Infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 1154; 09.01.2019

		PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
2211.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Esofil 40mg IV Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 38082 dated 19-11-2018 Rs.50,000/- Dated 16-11-2018
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	

	Submission by the firm: The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic(Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
2212.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad. **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Noctis 40mg IV Injection (Lyophilized powder for solution)
	Diary No. Date of R& I & fee	Dy.No 38081 dated 19-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Omeprazole as Sodium……40mg
	Pharmacological Group	PPI
		Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic (Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
2213.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-Penta injection IV
	Diary No. Date of R& I & fee	Dy. NO 633, 20-3-15, 50,000/-
	Composition	Each vial contains:- Pantoprazole lyophilized…….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Protonix by Wyeth (USFDA)
	Me-too status	Neege by Sami pharma

	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2214.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Albepra injection
	Diary No. Date of R& I & fee	Dy. NO 636, 20-3-15, 50,000/-
	Composition	Each vial contains:- Omeprazole sodium equivalent to omeprazole….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of Sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on

		contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2215.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-EZO injection
	Diary No. Date of R& I & fee	Dy. NO 634, 20-3-15, 50,000/-
	Composition	Each vial contains:- Esomeprazole (as Sodium)……..40mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished Product Specification	As per innovator
	Pack size & Demanded Price	1's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole of Consilient pharma (MHRA)
	Me-too status	Brince of ACE
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the

		request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2216.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Clida Gel 1%
	Diary No. Date of R& I & fee	Dy.No 43888 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Clindamycin Phospate eq to Clindamycin…1% 10mg
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	RESIDERM 1%w/w GEL by M/s Crawford Healthcare Limited (MHRA Approved)
	Me-too Status	Clindacin Gel 1%w/w by M/s Sante (Reg#067485)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	
2217.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sisul Cream, 1%
	Diary No. Date of R& I & fee	Dy.No 43886 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Silver Sulfadiazine…1% (w/w)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Silvadene Cream 1% of USFDA approved
	Me-too Status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	

2218.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jusidic Eye Drops
	Diary No. Date of R& I & fee	Dy.No 43887 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gm contains: Fusidic acid…1%
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucithalmic 1%w/w viscous eye drops, MHRA Approved
	Me-too Status	Fusitek Eye Drops 1% by M/s Invotek Pharma, Reg. No. 26957
	GMP Status	Same as stated above Ear/Eye Drops (General/Steroidal) section approved.
	Remarks of the Evaluator.	The firm has revised the formulation from 1% w/v to 1% w/w without submission of fee.
	Decision of 293rd meeting: Deferred for submission of applicable fee for revision of formulation. Submission by the firm: The firm has submitted the fee Rs. 5,000/- vide challan number 1932506 dated 12/08/2020. **Decision: Approved.**	
2219.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hisone 250mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42385 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Hydrocortisone sodium Succinate eq to Hydrocortisone…250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision of 295th meeting: Deferred for confirmation of section in M/s Rotex Pharma Pvt Ltd . Submission by the firm: The applicant has submitted Sterile Dry Powder Vial (Steroid) Section approval letter No. F.1-53/2003-Lic(Vol-I) dated 4th Dec, 2018 issued by Secretary Licensing Board. **Decision: Aprpproved.**	
2220.	Name and address of Applicant	M/s Excel Healthcare Laboratories Pvt Ltd. House. D#122, Block 4 Federal B Area Karachi, Pakistan.
	Name and address of manufacturer	M/s Pharma vision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey
	Marketing authorization holder	M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey
	Exporting country	Turkey
	Type of Form	Form 5-A

	Diary No. & Date of R& I	Dy. No 35530 Dated 25-10-2018
	Fee including differential fee	Rs. 50,000/- Dated 25-10-2018
	Brand Name +Dosage Form + Strength	Gembag 100mg/2ml Solution for IM Injection
	Composition	Each ampoule contains: Iron III hydroxide polymaltose complex….333.33mg (Eq. to 100mg elemental iron)
	Finished Product Specification	Firm claim In-House specification
	Pharmacological Group	Parenteral iron preparation
	Shelf life	24 Months
	Pack size & Demanded Price	2ml glass ampoule & As per SRO
	International availability	FERRUM H iron 100mg/2mL (as polymaltose) injection ampoule (TGA Australia)
	Me-too status	Reg No. 041029by M/s Schazo Pharma Lab.
	Stability studies	Firm has submitted long term (24 months) at 30+2ºC, 65+5%RH & accelerated (06 months) stability data at 40+ 2ºC, 75+ 5% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 2018/1000) issued on 07-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Pharmavision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey. This certificate is valid until 17-03-2020. • Original product specific Sole agency agreement dated 23rd March 2018 of importer M/s Excel Healthcare Laboratories Pvt Ltd with Product License Holder M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of differential fee i.e. 50,000/- since the applied formulation is already registered by DRAP. Evaluation by PEC: The firm has submitted differential fee Rs. 50,000/- vide challan number 2001025 dated 13/08/2020. **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm will provide valid CoPP for further processing of case.**	
2221.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Laderfex-D Tablet 60/12 0
	Composition	Each tablet contains:- Fexofendine HCl…….60mg Pseudoephedrine HCl……..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10954 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D Tab of Sanofi Aventis, USFDA
	Me-too status	Fenadrin D Tablet of Noa Hemis (Reg#042352)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division	

	Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
2222.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Hirafen-Plus Tablet 200mg/30mg
	Composition	Each film coated tablet contains:- Ibuprofen……200mg Pseudoephedrine HCl……..30mg
	Diary No. Date of R& I & fee	Dy. No 10824 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	NSAID/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Advil Cold and Sinus of Pfizer, USFDA
	Me-too status	Rovinac Tablets of Rock Pharma (Reg# 064206)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. **Decision: Approved with innovator's sepcifications.**	
2223.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Slorit-D Tablet 2.5/120
	Composition	Each tablet contains:- Desloratadine……2.5mg Pseudoephedrine Sulfate…..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10953 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067246)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well.	

	Decision: Approved.	
2224.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Slorit-D Tablet 5/240
	Composition	Each tablet contains:- Desloratadine……5mg Pseudoephedrine Sulfate…..240mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10955 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067247)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
2225.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals, 19 Km G.T. road, Kalashah Kaku, Lahore.
	Brand Name +Dosage Form + Strength	COLIMETH Dry powder for Injection
	Diary No. Date of R& I & fee	Dy.No. 35528 dated 25/10/2018 PKR 20,000/-
	Composition	Each vial contains; Colistimethate Sodium……1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Last inspection report dated 20/09/2017 concludes the overall condition of the firm as satisfactory.
	Remarks of the Evaluator.	
	Decision of 289th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Submission by the firm: The firm has submitted that lyophilized raw material will be imported and filled in General Powder Filling section. The firm has been granted Dry Powder Injection (General) Section vide section approval letter No. F.1-63/84-Lic (Vol-III-A) dated 3rd October, 2019. **Decision: Approved.**	
2226.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR-300 Tablets

	Diary No. Date of R& I & fee	Dy.No 41447 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Extended Release Tablet Contains: Quetiapine as Fumarate…300mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm: The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 300mg Tablet of M/s Hilton Pharma , Reg No. 76087. **Decision: Approved.**	
2227.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR 150 Tablets
	Diary No. Date of R& I & fee	Dy.No 41448 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…150mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm: The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 150mg Tablet of M/s Hilton Pharma , Reg No. 067501. **Decision: Approved.**	
2228.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Ceftax 250mg Injection
	Composition	Each vial contains: Cefotaxime (as cefotaxime sodium)……. 250mg
	Diary No. Date of R& I & fee	Dy. No. 10774 dated 05/03/2019 R. 20,000/- dated 05/03/2019
	Pharmacological Group	Antiobiotic

	Type of Form	Form 5
	Finished Product Specification	B.P
	Pack size & Demanded Price	1's, as per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Cefon injection 250mg (vial) of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision pf 291st meeting: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by CIMA Spain and the reference provided by the firm has been verified and given in the following; Caefotaxima Normon 250mg powder and solvent for injectable IV EFG (Status: Marketed). Each vial contains: Cefotaxime as sodium…… 250mg The website was accessed on 29/06/2020. https://cima.aemps.es/cima/publico/lista.html **Decision: Approved.**	
2229.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	CLOBAM Tablet 10mg
	Composition	Each tablet contains: Clobazam……..10mg
	Diary No. Date of R & I & Fee	Dy No.12236 dated 06-03-2019 ; Rs.20,000 06/03/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	B.P Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Onfi tablet (10mg, 20mg) by M/s Lundbecl Pharms LLC, USFDA Approved
	Me - too Status	Frisium tablet 10mg Reg No 2692
	G. M. P. Status	Inspection report dated 22/02/2019 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for scientific justification of overage present in the applied formulation.	
	Evluation by PEC: The firm has submitted revised formulation along with the master formula omitting the overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2230.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	DINOP – E2 Tablet 3mg
	Composition	Each tablet contains: Dinoprostone…….. 3mg
	Diary No. Date of R & I & Fee	Dy. No.6511 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Prostaglandin Analog
	Type of Form	Form 5

	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Prostin E2 vaginal tablet by M/s Pfizer MHRA Approved
	Me - too Status	Prostin E-2 by Pfizer vaginal tablets (Reg. No. 009821)
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The firm has applied for **oral tablet** while the product approved in reference authority is **Vaginal Tablet**.
	Decision of 293rd meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Evaluation by PEC: The firm has stated that it was a typographical error and Oral Tablet was written instead of Vaginal Tablet. The evidence of approval in reference authority and me-too status have already been verified as Vaginal tablet. Following is the correct label claim submitted by the firm. The firm has no tsubmitted any fee. Each vaginal tablet contains: Dinoprostone…….. 3mg **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2231.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	TENIL Tablet 6mg
	Composition	Each Tablet Contains: Bromazepam……6mg
	Diary No. Date of R & I & Fee	Dy. No.6506 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Apo-bromazepam tablet (1.5mg, 3mg, 6mg) by M/s Apotex Inc. Health Canada Approved
	Me - too Status	Yazd 6mg Tablet By M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65693
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation without overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2232.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.25mg
	Composition	Each Tablet Contains: Alprazolam……. 0.25mg

	Diary No. Date of R & I & Fee	Dy No.6501 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.25mg by M/s Pfizer, MHRA Approved
	Me - too Status	Lydia 0.25mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65697
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2233.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.5mg
	Composition	Each Tablet Contains: Alprazolam……. 0.5mg
	Diary No. Date of R & I & Fee	Dy No.6502 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.50mg by M/s Pfizer, MHRA Approved
	Me - too Status	Lydia 0.50mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65705
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2234.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 1 mg
	Composition	Each Tablet Contains: Alprazolam……. 1 mg
	Diary No. Date of R & I & Fee	Dy No.6503 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs

	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 1.0mg by M/s Pharmacia and Upjohns, USFDA Approved
	Me - too Status	Lydia 1.0mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65699
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2235.	**Name and address of manufacturer / Applicant**	**M/s Ciba Pharmaceutical private limitd, plot no.** A-371, Nooriabad site industrial Area, Super highway Karachi.
	Brand Name +Dosage Form + Strength	VOXY 100mg capsule
	Diary No. Date of R& I & fee	Dy.No.35275 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Doxycycline as hyclate…….100mg
	Pharmacological Group	tetracycline
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2, 5's×6, 5's×10, 5's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Doxycycline 100mg Capsules by M/s Kent Pharmaceuticals Ltd, MHRA Approved.
	Me-too Status	Medox Capsule 100mg by M/s Maxitech, Reg. No. 84781
	GMP Status	GMP certificate has been issued on 20/08/2019 based on inspection conducted on 07/08/2019.
	Remarks of the Evaluator.	The firm has revised the formulation from doxycycline monohydrate to Doxycycline as hyclate as per the composition of the reference product **without submission of Fee.**
	Decision of 293rd meeting: Deferred for submission of fee (Rs. 20,000/-) for revising the formulation from doxycycline monohydrate to Doxycycline as hyclate as per the composition of the reference product.	
	Evaluation by PEC: The firm has submitted Rs. 20,000/- vide challan no. 0768949 dated 11/03/2020 for revision of formulation as per the reference product. The following is the correct label claim of the applied product. Each capsule contains: Doxycycline as hyclate…….100mg **Decision: Approved.**	
2236.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Midaz 7.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38054 dated 19-11-2018 Rs.20,000/-
	Composition	Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg
	Pharmacological Group	Sedative/Hypnotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's price Rs. 200/-, 20's price Rs. 250/-

	Approval Status of Product in Reference Regulatory Authorities	Dormicum (7.5mg & 15mg) film coated Tablets by M/s CHEPLAPHARM Arzneimittel GmbH, Netherlands Approved.
	Me-too Status	Dorminic Tablets 7.5mg tablet by M/s Dosaco Laboratories, Reg No. 24295
	GMP Status	The firm was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). Alternate brand name: Mezolam Saf-mif • The firm has revised the formulation of applied product from **Midazolam as Hydrochloride** to **Midazolam as Maleate** and submitted fee Rs. 5000/- vide challan number 0828860 dated 12/12/2019.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	
	Evaluation by PEC: The firm has submitted remaining fee of Rs. 15,000/- vide challan number 0828873 dated 17/02/2020 for revision of formulation as per the reference product. Following is the correct label claim of the product. Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg **Decision: Approved with innovator's specifications.**	
2237.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	TARADOL tablet 37.5mg/325mg
	Diary No. Date of R& I & fee	Dy.No. 35264 dated 24/10/2018 PKR 20,000/-
	Composition	Each Film Coated tablet contains: Tramadol hydrochloride…….37.5mg Paracetamol…….325mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as recommended by PRC
	Approval Status of Product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP Status	Last inspection report dated 26/10/2018, the firm is not found working as required under the law rule.
	Remarks of the Evaluator.	
	Decision of 293rd meeting**:** Registration Board referred the case to QA & LT Division to conduct GMP inspection of firm on priority.	
	Evaluation by PEC: The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved.**	
2238.	**Name and address of manufacturer / Applicant**	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Diary No. Date of R& I & fee	Dy.No 35106 dated 23-10-2018 Rs.20,000/- Dated 22-10-2018
	Brand Name +Dosage Form + Strength	Velanef 800mg Tablets
	Composition	Each Film Coated Tablet Contains: Sevelamer HCL…800mg
	Pharmacological Group	Phosphate Binder

	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renagel 800mg Tablet by M/s Genzyme Corporation, (USFDA approved)
	Me-too status	Renavel 800mg Tablet by M/s AllianzeMed Pharmaceuticals (Reg No:075510)
	GMP status	26-10-2018. The firm is not found working as required under the law/rule
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for updated GMP status of the firm from QA&LT Division. **Evaluation by PEC:** The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved with innovator's specifications.**	
2239.	Duplication	
2240.	**Name and address of manufacturer / Applicant**	AJM Pharma, Plot No. 44, sector No. 27 korangi Inustrial Area Karachi
	Brand Name +Dosage Form + Strength	Asclop tablet 75mg/75mg
	Diary No. Date of R& I & fee	Dy. No. 1315 dated 03/05/2017 Re. 20,000/-
	Composition	Each film coated tablet contains: Clopidogrel as bisulfate…. 75mg Acetyl salicylic acid……75mg
	Pharmacological Group	ADP induced platelet aggregation inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 220/- per pack of 10's
	Approval Status of Product in Reference Regulatory Authorities	CoPlavix Tablet Clopidogrel (as hydrogen sulfate) and aspirin by M/s sanofi-aventis, (TGA Approved)
	Me-too Status	Clodril Plus Tablet M/s Macter International, Reg. No. 55982
	GMP Status	Same as for the previous case
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). Alternate brand names: Asplat Clopiclot
	Decision of 293rd meeting: Deferred for clarification of the dosage of the Innovator product, whether bilayer tablet or otherwise. Evaluation by PEC: The firm has submitted the applied product is not bilayered while it is immediate release film coated tablet. The statement has not been verified from EMA assessment report. The product approved in EMA is bilayered. **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee along with the proof of availability of bilayer tabletting machine.**	
2241.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.2
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….20mg
	Composition	Dy. No. 7989 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors

	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ezetimibe and Atrovastatin calcium (USFDA)
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section. Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
2242.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.4
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….40mg
	Composition	Dy. No. 7990 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ezetimibe and Atrovastatin calcium (USFDA)
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section. Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
2243.	Name and address of manufacturer/Applicant	M/s Pharmix Laboratories (Pvt.) Ltd., 21-km, Ferozepur Road, Lahore

	Brand Name +Dosage Form + Strength	Prozol Capsule 30mg
	Composition	Each capsule contains: Enteric coated pellets eq. to Lansoprazole….30mg (Source of Pellet M/s Murli Krishna Pharma Pvt. Ltd. D-98, Ranjangaon, Taluka-Shirur, Pune 412209 Maharashtra state, India)
	Diary No. Date of R& I & fee	Dy. No. 32736 dated 02-10-2018, Rs. 15,000/- dated 15-10-2009, and Rs. 85000/- dated 22-09-2016
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs.425/Pack of 14's
	Reference Regulatory Authorities status	Lansoprazole 30 mg gastro-resistant capsules (UK)
	Me-too status	Arcozol Capsules 30mg of M/s Pakistan Pharmaceutical Products (Pvt) Ltd, Karachi
	GMP status	GMP inspection by inspectors dated 31-05-2018 & 01-06-2018 shows the acceptable level of compliance of GMP.
	Remarks of the Evaluator	Provided stability studies of Lansoprazole pellets 8.5%w/w at 30±2^{0}C, 65%±5% RH of 12 months and at 25±2^{0}C, 60%±5% RH of 48 months
	Decision of 293rd meeting: Deferred for submission of stability data of pellets through shelf life as per Zone IVA. Submission by the firm**:** The firm has submitted long term stability study data of 03 batches for 36 months period according to the conditions of zone IV-A. However, accelerated stability data is not submitted. **Decision: Deferred for submission of Accelerated Stability data of 03 batches of pellets.**	
2244.	Name and address of manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories, Plot # 9A, St#N-5, National Industrial Zone, (RCCI) Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Soulpride 50mg Tablet
	Diary No. Date of R& I & fee	Diary No, Date of R & I & fee Dy. No. 22438 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Composition	Each tablet contains: Levosulpride……..50mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Inovator's specification
	Pack Size & Demanded Price	20's & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	
	Me-too Status	Sulprex Tablets 50mg of M/s Global Pharmaceuticals GMP Status DML by way of formulation No. 000871 dated 13-09-2017.
	GMP Status	Could not be confirmed
	Remarks of the Evaluator.	
	Decision of 292nd meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by AIFA Italy. LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved. Each tablet contains: Levosulpride……..50mg GMP status of the firm could not be confirmed. **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	

2245.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, Faisalabad Road Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 60mg Injection
	Composition	Each vial contains: Artesunate ……60mg
	Diary No. Date of R& I & fee	Dy. No 28674 Dated 27-08-2018, Rs. 50,000/- dated 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Gen-M 60mg Injection of M/s Genix Pharma (Pvt) Ltd.
	GMP status	M/s Nabiqasim Industries Pvt. Ltd: DML by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP M/s Surge Laboratories Pvt. Ltd: cGMP inspection dated 05-05-2019 shows good level of cGMP compliance of the firm.
	Remarks of the Evaluator	
	Decision of 292nd meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Now the firm has submitted the evidence of WHO recommended formulation which is access dated 06th December 2019 http://archives.who.int/eml/expcom/expcom15/applications/formulations/artesunate.pdf Decision of 293rd meeting: Deferred for evidence of approval of requisite manufacturing facility from licensing division. Submission by the firm: The applicant has submitted that M/s Surge Laboratories was granted Additional section of Dry Powder Injectable (General) vide letter No. F.1-18/95-Lic(Vol-III) dated 7th July, 2020. The copy of letter is attached with the submission. **Decision: Approved with innovator's specifications.**	

Case No. 2. Registration Applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases (Local manufacturing) Veterinary

2246.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	MAXIFLOR 30% Oral Liquid
	Diary No. Date of R& I & fee	Dy.No. 35265 dated 24/10/2018 PKR 20,000/-
	Composition	Each 100ml contains: Florfenicol……30% (w/v)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack Size & Demanded Price	Plastic bottle of 100ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 18/08/2017 concludes the overall GMP compliance level as good.
	Remarks of the Evaluator.	Evidence of applied formulation/drug already

		approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

b. Deferred cases (local manufacturing) Veterinary

2247.	Name and address of Applicant/ Manufacturer	M/s Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur
	DML	DML by way of formulation dated 25-10-2015.
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 16299 Dated 03-05-2018
	Fee including differential fee	Rs. 20,000/- Dated 02-05-2018
	Brand Name +Dosage Form + Strength	MOXY CS POWDER
	Composition	Each 1000gram contains: Amoxicillin Trihydrate……150gm Colistin sulphate……25gm
	Finished Product Specification	Firm claim innovator's specification
	Pharmacological Group	Antibiotic
	Demanded Price	Decontrolled
	Pack size	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg
	Me-too status	Moxicoli water soluble powder of m/s zumars pharma (pvt) ltd. Karachi.
	GMP status	GMP inspection dated 03-10-2018 **Conclusion:** During the inspection, some suggestions were given for improvement and certain shortcomings were also identified. The Firm's management looked committed in rectifying the shortcomings and assured to do so in the shortest possible time. Therefore, keeping in view the environmental, manufacturing and quality control facilities provided, discussions made with the technical personnel, the documentations presented and reviewed, the raw materials consumed in manufacturing of the registered products and commitment of the firm's management in rectifying the shortcomings, the firm M/s Farm Aid Group Haripur is considered to be maintaining satisfactory level of the cGMP and found to be fulfilling GMP requirements
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for evidence of approval of requisite maujfacturing facility (penicillin) from licensing division. **Submission by the firm:** The firm has submitted approval letter No.F.3-9/91-Lic(Vol-I) dated 21st June, 2017 for Dry Powder Section (Vet) section. **Decision: Deferred for confirmation of required manufacturing facility "Dry Powder penicillin (Veterinary)" section.**	

Case No. 3: **Registration Applications of Newly Granted DML or New Section (Veterinary)**

a. New Section:
Vet New Section

M/s Medi-Excel Pharmaceutical, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad was granted additional sections vide letter no. F.1-2/2001-Lic (Vol-I) dated 29/09/2019. The firm has applied for following products against relevant sections as under.

GENERAL INJECTABLE SECTION (VET) NEW One product/molecule was approved in 294th meeting of Registration Board in General Injectable Section (Vet). Further 9 molecules and 29 products are remaining.		
NO OF MOLECULES		**NO PRODUCTS**
9		**31**
2248.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20823 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2249.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20824 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2250.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20825 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)

	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2251.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20826 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2252.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20827 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2253.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20828 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

2254.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20829 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2255.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20830 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2256.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains: Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20831 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2257.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains:

		Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20832 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2258.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"
	Diary No. Date of R& I & fee	Dy. No 20833 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2259.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"
	Diary No. Date of R& I & fee	Dy. No 20834 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2260.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20835 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification

	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2261.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20836 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2262.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20837 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2263.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20838 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No.

		000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2264.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20839 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2265.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20840 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2266.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20841 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection 100ml vial of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
	Name and address of manufacturer /	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282

2267.	Applicant	Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20842 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2268.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20843 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2269.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20844 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No.

		000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2270.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20845 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2271.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20846 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2272.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20847 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Forte Injection **50ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 102087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.

	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2273.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20848 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec forte injection 50ml vial by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2274.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20849 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec forte injection **50ml vial** by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2275.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone……. 50 mg"
	Diary No. Date of R& I & fee	Dy. No 20853 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5

	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2276.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone…….50 mg"
	Diary No. Date of R& I & fee	Dy. No 20854 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The applied filled volume of 50ml is not approved while other filled volumes that 10ml, 20ml, 40ml and 100ml are approved.
	Decision: The Board approved the case with innovator's specifications with a filled volume of 50mL as already approved filled volumes range from 10mL to 100mL.	
2277.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	" Each ml contains: Closantel……...50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20857 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specfiications.	
2278.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	"Each ml contains: Closantel……...50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20858 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification

	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
BOLUS SECTION (VET) NEW		
NO OF MOLECULES		**NO PRODUCTS**
10		13
2279.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 152 Bolus
	Composition	"Each bolus contains: Albendazole……..152 mg"
	Diary No. Date of R& I & fee	Dy. No 20810 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-S Bolus 152mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043139)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2280.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 600 Bolus
	Composition	" Each bolus contains Albendazole……600 mg"
	Diary No. Date of R& I & fee	Dy. No 20811 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-C Bolus 600mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043138)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2281.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 2500 Bolus
	Composition	" Each bolus contains Albendazole……2500 mg"
	Diary No. Date of R& I & fee	Dy. No 20812 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage	Albensel-2500 Bolus 2500mg of M/s Selmore

	form)	Pharmaceuticals Pvt Ltd, (Reg.# 043137)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2282.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flumexcel 350 Bolus
	Composition	" Each bolus contains Flumequine…….350 mg"
	Diary No. Date of R& I & fee	Dy. No 20813 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Flumequine Bolus 350mg of M/s Zakfas Pharmaceuticals Pvt Ltd, (Reg.# 074754)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2283.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Fenexcel 750 Bolus
	Composition	"Each bolus contains: Fenbandazole…….750 mg"
	Diary No. Date of R& I & fee	Dy. No 20814 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Fenbal-Bolus 750mg of M/s Wimits Pharmaceuticals Pvt Ltd, (Reg.# 078319)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2284.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nicloexcel 1250 Bolus
	Composition	"Each bolus contains: Niclosamide……1250 Mg"
	Diary No. Date of R& I & fee	Dy. No 20815 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Niclover Bolus 1250mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046572)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications.	
2285.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Santexcel 500 Bolus
	Composition	"Each Bolus contains: Closantel…….500 Mg"
	Diary No. Date of R& I & fee	Dy. No 20816 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Flukinil Bolus 500mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046571)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2286.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Trileva 99 Bolus
	Composition	"Each Bolus contains: Triclabendazole……900 mg Levamisole HCl……90 mg"
	Diary No. Date of R& I & fee	Dy. No 20817 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribazole Plus Bolus 900mg/90mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 074039)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2287.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Trissen 1000 Bolus
	Composition	"Each Bolus contains: Trimethoprim……200 mg Sulphadiazine ……..1000 mg"
	Diary No. Date of R& I & fee	Dy. No 20818 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribactral Bolus 200mg/1000mg of M/s Selmore Pharmaceuticals, (Reg.# 029617)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2288.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700,

		Pakistan"
	Brand Name +Dosage Form + Strength	Suldimexcel 2.5 Bolus
	Composition	"Each Bolus contains: Sulphadimidine Sodium…….2.5 Gm"
	Diary No. Date of R& I & fee	Dy. No 20819 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Sulfapri Bolus 2.5gm of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 063683)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2289.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermexcel Bolus
	Composition	"Each Bolus contains: Levamisole HCl……1125 mg Oxyclozanide……2250 mg"
	Diary No. Date of R& I & fee	Dy. No 20820 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Zanisol Bolus1125mg/2250mg of M/s Prix Pharmaceuticals, (Reg.# 044979)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2290.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 400 bolus
	Composition	"Each bolus contains: Levamisole HCl……..400 mg"
	Diary No. Date of R& I & fee	Dy. No 20821 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	LEVA 400 BOLUS of M/s Intervac, (Reg.# 072651)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2291.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 1125 Bolus
	Composition	"Each bolus contains: Levamisole HCl……..1125 mg"

	Diary No. Date of R& I & fee	Dy. No 20822 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Levasel Bolus 1125mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 029618)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

Case No. 4: **Registration Applications of Import Cases.**

a. New Cases Human Import

2292.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.
	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No: 8137 Dated : 25/02/2019
	Fee including differential fee	Rs: 50,000 Dated : 25/02/2019
	Brand Name +Dosage Form + Strength	Amomax 3g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…….2g Salbactum sodium equivalent to Salbactum……..1g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 608/- per vial (1's)
	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	N/A
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052203 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.
	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China authorized M/s biocare.

	Decision: Approved as per policy for inspection of manufacturer abroad.	
2293.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.
	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 8136 Dated : 25/02/2019
	Fee including differential fee	Rs : 100,000 Dated : 25/02/2019
	Brand Name +Dosage Form + Strength	Amomax 1.5g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…. 1g Salbactum sodium equivalent to Salbactum….. 0.5g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 407/- per vial (1's)
	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	To be confirmed
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052202 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.
	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2294.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	Drug license by way of whole sale Address: Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2, 2nd floor West Land trade centre plot no. C-5, Block 7/8, KCHSU, Shaheed e Millat road Karachi. Validity: 09/10/2020
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1674 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 40mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)……40mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 27/- per Cap
	International availability	Losec Capsule 40mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.
	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Sole agency agreement is required. Free sale certificate is issued by authority not recognized by WHO.
	Decision: Deferred for submission of sole agency agreement/letter of authorization and confirmation of zone stability under stability studies were conducted..	
2295.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1673 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 20mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)..……20mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 20/- per Cap
	International availability	Losec Capsule 20mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 20mg by M/s Scotmann Pharmaceuticals (Reg#028238)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.

	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Original sole agency agreement is required. Free sale certificate is issued by authority not recongnized by WHO.
	Decision: Deferred for submission Sole Agency Agreement/letter of authorization.	
2296.	Name and address of Applicant	M/s Aster Life Sciences, 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore. Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1215 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 500mg IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..500mg
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 500 mg powder for solution for injection or infusion by M/s Milpharm Limited, MHRA Approved.
	Me-too status	Mopen 500mg Injection by M/s Hilton pharma, Reg. No. 36429.
	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1738 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018 **Free sale:** Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference

		regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied fromulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to deferred the case for clarification of salt form.	
2297.	Name and address of Applicant	M/s Aster Life Sciences , 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore. Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1216 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 1g IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..1g
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 1g powder for solution for injection or infusion by M/s Hikma, MHRA Approved.
	Me-too status	Mopen 1g Injection by M/s Hilton pharma, Reg. No. 36427.
	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1736 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018 **Free sale:** Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied formulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to defer the case for clarification of salt form.	

2298.	Name and address of Applicant	M/s Scilife Pharma (pvt) Limited, Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Laboratorio Eczane Pharma S.A, Laprida 43, Avellaneda, Buenos Aires, Argentina.
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 6951 Dated 19/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 19/02/2019
	Brand Name +Dosage Form + Strength	Xelotab 500mg tablet
	Composition	Each film coated tablet contains: Capecitabine……..500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	24 months
	Pack size & Demanded Price	2083.3/- per 10's, 6250/- per 30's, 12500/- per 60's, 25000/- per 120's
	International availability	Capecitabine 500 mg film-coated tablets by M/s Glenmark Pharmaceuticals Europe Limited, MHRA Approved.
	Me-too status	MERICAP 500MG film coated tablet by M/s Merixil pharma, Reg. No. 81801
	Stability studies	24 months data for real time and 6 months of accelerated data.
	Detail of certificates attached	**Original CoPP** **Certificate No**: 191912 **Certified by:** National Institute of drugs **Date of issuance:** 28/08/2018 **Free sale:** Yes **GMP status:** The facilities and operations conform to WHO-GMP as per CoPP.
	Remarks of the Evaluator.	Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature* *that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16598/2020* *Tariff: 6.12.3* *Amount: ARS 300/-* *Date: 01/20/2020* *Observations*
	Decision: Deferred for review of stability data as per Zone IVA	
2299.	Name and address of Applicant	M/s Zam Zam Pharmaceutical, Suit No. 205,206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi, Pakistan.

	Detail of Drug Sale License	Drug license by way of Wholesale Address: Zam Zam Pharmaceutical , Suit no. 16 Beaumont Road Karachi. Validity: 15/02/2022
	Product License Holder & Manufacturer	**Manufacturer (**Primary and secondary packaging**):** M/s Haupt Pharma amareg GmbH Donaustaufer Strasse 378 DE-93055 Regemsburg, Germany **Analysis and batch release:** M/s Medinova AG Eggbuhlstrasse 28 Zurich, Switzerland **Product License Holder:** Medinova AG Eggbuhlstrasse 28 CH-8050 Zurich Switzerland
	Name of exporting country	Switzerland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 29862 Dated 05/09/2018
	Fee including differential fee	Rs. 50,000/- Dated 05/09/2018 Rs. 5,000/- dated 19/05/2020 for change of product license holder.
	Brand Name +Dosage Form + Strength	Gynoflor Vaginal tablets
	Composition	Each vaginal tablet contains: Lactobacillus acidophilus……100million cfu Estriol……...0.03mg
	Finished Product Specification	Innovators
	Pharmacological Group	Gynecological anti-infective and antiseptic
	Shelf life	36 months
	Pack size & Demanded Price	1 blister of 6 vaginal tablets, Rs. 1875.
	International availability	Approved in Switzerland as per CoPP and the approval status has been verified from official website. Gynoflor vaginal tablet by M/s medinova, Swissmedic
	Me-too status	Could not be confirmed
	Stability studies	36 months data of 3 batches at 5°C±3°C, 60%±5%, Real Time 06 months data of 3 batches at 25°C± 3°C, 60%±5%, Acelerated
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 20001402 **Certified by**: Swissmedic **Date of issuance:** 20/03/2020 **Free sale:** yes **GMP status:** conforms to WHO-GMP Copy of Distribution agreement is submitted. M/s Medinova AG, Switzerland confirms M/s Zam Zam Pharmaceutical as the exclusive distributor for Pakistan.
	Remarks of the Evaluator.	Lactobaccilus bacilus is a living organism, therefore the content of lactobacillus aciophilus in lyophilisate may vary within the specifications. Manufacturing: 1. Manufacturing of Premix of estriol with cellulose 2. excipients + Acidophilus bacillus lyphilisate Resultant mixtures from both steps ar then finally mixed and compressed.
	Decision: Referred to Committee constituted by DRAP for determining therapeutic group.	
2300.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.

	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5744 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SPDROX 500mg capsule
	Composition	Each capsule contains: Hydroxyurea ……500mg
	Finished Product Specification	BP
	Pharmacological Group	antineoplastic (anti-cancer)
	Shelf life	24 Months
	Pack size & Demanded Price	10's & As per SRO
	International availability	Hydroxycarbamide medac 500 mg capsule, hard (Germany)
	Me-too status	HYDREA CPASULES 500MG of M/s BRISTOL MYERS SQUIBB
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2301.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5745 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SP GEF 250mg tablet
	Composition	Each film coated tablet contains: Gefitinib……250mg
	Finished Product Specification	Firm claim in-house specifications of applied product
	Pharmacological Group	Anticancer
	Shelf life	24 Months
	Pack size & Demanded Price	As per SRO
	International availability	Gefitinib 250 mg film-coated tablets of M/s Cipla (Eu) Ltd., (MHRA approved)
	Me-too status	Could not be confirmed
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of

		Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	Me too status could not be confirmed.
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2302.	Name and address of Applicant	M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi
	Detail of Drug Sale License	Address: M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi Validity: 24-12-2018 to 23-12-2020 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.
	Name and address of marketing authorization holder	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7465 Dated 04-07-2017
	Fee including differential fee	Rs. 100,000/- Dated 25-08-2014 copy attached.
	Brand Name +Dosage Form + Strength	Cytodrox Hydroxyurea Capsules USP 500mg
	Composition	Each capsule Contains: Hydroxyurea…….500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	36 months: Store below 30°C.
	Pack size & Demanded Price	10's & As per DPC
	International availability	Hydrea 500 mg Hard Capsule by M/s Bristol myer, MHRA Approved.
	Me-too status	Uro-Z 500mg Capsule by M/s Zjans Pharma, Reg. No. 26792
	Stability studies	Firm has submitted long term (36 months) at 30°C & accelerated (06 months) stability data at 40°C, 75± 5% RH for three batches.
	Detail of certificates attached	Legalized and valid copy of CoPP Certificate No. 789.MFG/WHO-GMP/DFA/2019/164(2) valid till 19/02/2022 is submitted. The product is available I for free sale in country of origin and the manufactuere conforms to WHO-GMP as per CoPP. Copy of agreement is attached.
	Remarks of the Evaluator.	ii. Photocopy of fee challan form is attached.
	Decision: Approved with as per Policy for inspection of Manufacturer abroad. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2303.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore
	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020 Address: 73-B Guldashat town, Zarrar Shaheed Road, District Lahore. *the firm has submitted receipt for renewal of license.

	Product License Holder & Manufacturer	M/s S.C. Magistra C&C S.R.L 82A Aurel Vlaicu blvd., Constanta, code 900055, Romania
	Name of exporting country	Romania
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 7571 Dated 28-02-2018
	Fee	Rs. 50,000/- Dated 28-02-2018
	Brand Name +Dosage Form + Strength	Contracept M 18.9mg Pessary
	Composition	Each pessary contains: Benzalkonium chloride……18.9mg
	Finished Product Specification	
	Pharmacological Group	Act code G02BBN2 Local contraceptives
	Shelf life	24 Months
	Pack size & Demanded Price	10's commercial unit & As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed
	Stability studies	Firm has submitted long term (24 months) at $30^{o}C \pm 2^{0}C$, 65%RH±5%RH & accelerated (06 months) stability data at $40^{o}C$, 75% RH of three batches
	Detail of certificates attached	Legalized and valid copy of CoPP (Certificate#. 5487) issued on 11-10-2017 by Ministry of Health, National Agency for Medicines and Medical Devices declaring the free sale of applied product and GMP compliant status of the manufacturer. Copy of Original Notarized "Product specific Letter of Authorization" from M/s VEM Llac San. Ve Tic. A.S in the name of M/s Bristol Mayer Biotech Pakistan dated 07-06-208 valid for 2 years is submitted
	Remarks of the Evaluator.	iv. The product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP. v. Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. vi. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the submission of following; • **Calrification is required since the product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech**	

b. Deferred Cases (Human) Import

2304.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Manufacturer & Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A

	Diary No. & Date of R& I	Dy. No 3702 Dated 28-01-2019
	Fee including differential fee	Rs. 100,000/- Dated 28-01-2019
	Brand Name +Dosage Form + Strength	DASANIB 70mg Tablet
	Composition	Each film coated tablet contains: Dasatinib…….70mg (as Dasatinib monohydrate 72.58mg)
	Finished Product Specification	In-house
	Pharmacological Group	ANTINEOPLASTIC AGENTS, L01XE Protein kinase inhibitors
	Shelf life	24 Months store below 300C
	Pack size	60's
	International availability	SPRYCEL 70mg (USFDA)
	Me-too status	SPRYCEL 70MG TABLETS of M/s BRISTOL-MYERS SQUIBB,
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 20132019 000767 18) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Valid for twelve months Copy of Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 293rd meeting: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. Submission by the firm: The firm has submitted Original and Valid CoPP (certificate No. 191910) issued by National institute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16599/2020* *Tariff: 6.12.3* *Amount: ARS 300 -* *Date: 01/20/2020* *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2305.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina

	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36523 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 100mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……100mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temoeirgen 100Mg Capsules of M/s Merixil Pharma
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"

Decision of 291st meeting of Registration Board:
Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP.

"Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic".
Decision:
Decision of 293rd meeting: Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP.
Submission by the firm: The firm has submitted Original and Valid CoPP (certificate No. 191914) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP.
Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following.
The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.
Holder / s of the document: LABORATORIO ECZANE PHARMA SA
Order No: 16598/2020
Tariff: 6.12.3
Amount: ARS 300 .-

	Date: 01/20/2020 *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2306.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Details of Drug sale license	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36524 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 250mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……250mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temonat 250mg Capsules of M/s Hakimsons
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 291st meeting of Registration Board: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. "Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic" **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP. **Submission by the firm:** The firm has submitted Original and Valid CoPP (certificate No. 191913) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP.	

	Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16597/2020* *Tariff: 6.12.3* *Amount: ARS 300 .-* *Date: 01/20/2020* *Observations* **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2307.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore
	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020
	Product License Holder & Manufacturer	M/s VEM Llac San. Ve Tic. A.S. Factory address: Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi. Fatih Bulvari. No: 38 Kapakli/ TEKIRDAG/TURKEY
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18447 Dated : 21/05/2018
	Fee including differential fee	Rs : 50,000 Dated : 21/05/2018 + Rs : 50000 :Dated: 16-10-2019
	Brand Name +Dosage Form + Strength	Candisept 100mg/50ml I.V Solution for Infusion
	Composition	Each 50ml Vial Contains Fluconazole ……100mg
	Finished Product Specification	USP
	Pharmacological Group	Antifungal
	Shelf life	36 Months
	Pack size & Demanded Price	As per SRO
	International availability	Fluconazole 2mg/ml Solution for Infusion (USFDA)
	Me-too status	Lumen 2mg/Ml Injection (50ml) Of M/S Nimrall Farma (Reg # 039823)
	Stability studies	
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/1719 **Certified by:** Turkish Medicines and Medical devices Agency *Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey* Product license and date of issue : 254/16 _05.11.2013 **Valid until :** 03-05-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **GMP certificate and Free sale certificate** Certificate No : 2018/1720 Date of Issue: 03-05-2018 Valid until : 03-05/2020

		GMP certificate: GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **Sole Contract Agreement** 07-06-2018 Validity: 2 Years	
	Remarks of the Evaluator.	**Deficiencies/Shortcomings**	**Reply by Firm**
		Remaining fee of Rs:50000/- as product is already registered in Pakistan.	Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1914215 Dated: 16-10-2019
		Justify use of Type II glass as primary packaging material while in reference agency Type I glass is used as primary packaging material.	According to the European Pharmacopoeia "3.2.1 Glass Containers for Pharmaceuticals Use" Type II glass containers are suitable for most acidic and neutral ,aqueous preparations whether or not for parenteral administration. Our product is near neutral and aqueous solution. Therefore, Type II glass is suitable for this product.
	Decision of 293rd meeting: Deferred for Clarification/Justification on scientific grounds for use of Type II glass container as primary packaging material for applied formulation or otherwise evidence of reference product packed in Type II glass container. **Evaluation by PEC:** The firm has provided the reference of the following product approved by MHRA which has been verified with following details; Fluconazole 2 mg/ml Solution for Infusion **2. Qualitative and quantitative composition** 50 ml/100 ml glass vials: 1 ml solution for infusion contains 2 mg of fluconazole. **6.5 Nature and contents of container** Glass vials: Clear type I or II glass vial, sealed with chlorobutyl rubber stopper and sealed with a flip-off aluminium cap. The official website was accessed on 29/06/2020. https://mhraproductsproduction.blob.core.windows.net/docs/c10d2a9d32a84c9c845161dedc2e587247c0ff58 **Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech**		
2308.	Name and address of Applicant	M/s Punjab Medical Services, Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore	
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. OPD Gate sir Ganga ram Hospital Mozang Road Lahore License to sell drugs as a Distributor No. 0011000 0002884 Valid upto 27th Feb. 2021	
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul, 34906, Turkey	
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE	
	Name of exporting country	Greece	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy. No 7371 Dated 20-02-2019	
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019	
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 50mg/vial	
	Composition	Caspofungin Acetate 55.52mg eq. to Caspofungin……50mg	
	Finished Product Specification	In-house	
	Pharmacological Group	Antimycotics for systemic use	

	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's
	International availability	CANCIDAS® 50 mg powder for concentrate for solution for infusion (Netherland)
	Me-too status	Not available
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129338) dated 09-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. **Submission by the firm:** The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland. It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2309.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE
	Name of exporting country	Greece
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7370 Dated 20-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 70mg/vial
	Composition	Caspofungin Acetate 77.69mg eq. to Caspofungin……70mg
	Finished Product Specification	In-house
	Pharmacological Group	Antimycotics for systemic use

	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's
	International availability	CANCIDAS® 70 mg powder for concentrate for solution for infusion (Netherland)
	Me-too status	Not Available
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129337) dated 08-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. Submission by the firm: The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland. It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2310.	Name and address of Applicant	M/s Mehran International 498 C Hume Road Quaideen Colony Opp: World Map Near 3 Star Hall Karachi-Pakistan
	Manufacturer & Product License Holder	M/s Hebei New Century Pharmaceutical Co. Limited 189 Taihang Street, Hi-tech zone Shijiazhuang, Hebei, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 31413 Dated 18-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-09-2018
	Brand Name +Dosage Form + Strength	Cefquinome Oral Suspension 2.5% 100ml
	Composition	Each ml contains: Cefquinome sulfate…….25mg
	Finished Product Specification	Firm claim innovators specification
	Pharmacological Group	fourth-generation cephalosporin antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1x100ml bottle Oral Suspension
	RRA status	Combactan of MSD USA

	Stability studies	Firm has submitted long term (36 months) at 30+2oC, 65+5%RH & accelerated (06 months) stability data at 40+ 2oC, 75+ 5% RH for three batches.
	Detail of certificates attached	Copy of CoPP is submitted Copy of Provided Sole agency agreement with M/s NINHUA Group Co., Ltd, 21 Jiangxia st. Ningbo, P.R. China which is sole and exclusive exporting subjected products of the manufacturer in Pakistan and manufacturer shall not sell the above-mentioned items to Pakistan marketed by itself or through any other third parties.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of original legalized CoPP from concerned regulatory Authority of exporting country. Submission by the firm: The firm has submitted original legalized CoPP (no.2019121601) issue dby Agricultural office of Shijiazhuang High-tech zone, China on 16/12/2019. The product is available in free sale. The facilitie and operations conform to WHO-GMP. **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	

Miscellaneous deferred cases of Import (Human)

Registration Board in 295th meeting had decided to defer the below mentioned 5 cases and decided that the Secretary Registration Board will confirm from the manufacturer (M/a Shanxi PUDE Pharmaceutical Co., Ltd., MAH Holder) via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.
The reply received from the relevant firm is being reproduced hereby before the Board.
1.
---------- Forwarded message ---------
From: **普德** <pudepharma@yeah.net>
Date: Thu, 3 Sep 2020, 12:46 pm
Subject: Confirmation of Authenticity of Stability Data
To: <abroabdullah@gmail.com>
Dear Abdullah,

Thanks for your email. We confirmed stability data of products for the batches mentioned in below mentioned table is true.

Sr.#	Brand name & Composition	Stability Batch No. & Manufacturing Date
1.	METHOTREXATE for IV injection 50mg/vial Each vial contains: Methotrexate…. 50mg	Batch No: 1845027 Mfg date: June 5, 2017 Batch No: 1845028 Mfg date: June 6, 2017 Batch No: 1845029 Mfg date: June 07, 2017
2.	METHOTREXATE for IV injection 100mg/vial Each vial contains: Methotrexate…. 100mg	Batch No: 19456620 Mfg date: July 09, 2017 Batch No: 19456621 Mfg date: July 10, 2017 Batch No: 19456622 Mfg date: July 11, 2017
3.	METHOTREXATE for IV injection 500mg/vial Each vial contains: Methotrexate…. 500mg	Batch No: 2010100 Mfg date: Aug 15, 2017 Batch No: 2010101 Mfg date: Aug 16, 2017 Batch No: 2010102 Mfg date: Aug 18, 2017

4.	VINORELBINE 10mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg	Batch No: 21000401 Mfg date: Sep 15, 2017 Batch No: 21000402 Mfg date: Sep 16, 2017 Batch No: 21000403 Mfg Date: Sep 17, 2017
5.	VINORELBINE 50mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg	Batch No: 21000404 Mfg date: Sep 18, 2017. Batch No: 21000405 Mfg date: Sep 19, 2017. Batch No: 21000406 Mfg Date: Sep 19, 2017.

Best regards
Shanxi PUDE Pharmaceutical Co., Ltd
Submitted for consideration of the Board.

2311.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3555 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 50mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 50mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.

	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: e. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true f. Detail of diluent to be used for reconstitution. g. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. h. Original, legalized and valid CoPP Evaluation by PEC: e. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (1845027 Mfg date:June5, 1845028 Mfg date: June 6, 2017, 1845029 Mfg date:June 07 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. f. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. g. The product approved in USFDA with same strength and dosage form that is 50mg Powder For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 50mg/2ml solution for injection is approved in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. h. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2312.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3556 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 100mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 100mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	

	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: d. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true e. Detail of diluent to be used for reconstitution. f. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: e. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (19456620 Mfg date:July 09, 19456621 Mfg date: July 10, 2017, 19456622 Mfg date: July 11, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. f. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. g. The product approved in USFDA with same strength and dosage form that is 100mg For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 100mg/4ml solution for injection is available in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. h. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2313.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3558 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017

	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 500mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 500mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150011) issued by Shanxi Food and Drug Administration valid till 03/11/***2017*** *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: d. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true e. Detail of diluent to be used for reconstitution. f. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: e. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (2010100 Mfg date: Aug 15, 2010101 Mfg date: Aug16, 2017, 2010102 Mfg date: Aug 18, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. f. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. g. The product (500mg for injection) with same strength and dosage form is not available in reference authorities while 500mg/20ml solution for injection is discontinued for reasons other than safety and efficacy. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. h. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2314.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan

	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 395 Dated 16-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 15-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 10mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 10mg/ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 10mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: f. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true g. Detail of diluent to be used for reconstitution. h. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. i. The salt form of the drug as it is different from the approved product in reference countries. j. Finished product specifications. Evaluation by PEC: g. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. h. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection. i. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted. j. Firm submitted CFDA standard specification.	

	k. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000401 Mfg date: Sep 15, 2017, 21000402 Mfg date: Sep 16, 2017, 21000403 Mfg Date: Sep 17, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. l. Salt form	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2315.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3560 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 50mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 50mg/5ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 50mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: g. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true h. Detail of diluent to be used for reconstitution.	

i. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
j. The salt form of the drug as it is different from the approved product in reference countries.
k. Finished product specifications.
l. Sole agency agreement

Evaluation by PEC:

g. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL.
h. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection.
i. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted.
j. Firm submitted CFDA standard specification.
k. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000404 Mfg date: Sep 18, 2017, 21000405 Mfg date: Sep 19, 2017, 21000406 Mfg Date: Sep 19, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data.
l. Salt form

Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.

Decision: Approved with innovators specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.

Registration Board in 295th meeting had decided to defer the below mentioned 02 cases and decided Secretary Registration Board will confirm from the manufacturer via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.

The reply received from the relevant firm is being reproduced hereby before the Board.

Dear ABDULLAH
Sorry for my late reply.
we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg: Each ampoule (2mL) contains: Irinotecan hydrochloride trihydrate……40mg	19277800	Oct 20, 2017
		19277801	Oct 21, 2017
		19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg: Each ampoule (5mL) contains: Irinotecan hydrochloride trihydrate……100mg	19277803	Oct 23, 2017
		19277804	Oct 24, 2017
		19277805	Oct 25, 2017

Please see attachment for STATEMENT.
Best regards!
Anna
Cisen Pharmaceutical Co., Ltd.
Add: Tongji Sci-tech Industrial Park, High-tech Industrial Development Zone, Jining, Shandong, P.R. China. 272073
Tel: +86 537 2980071 +86-18678761518
---------- Original ----------
From: "wangsh"<wangsh@cisengroup.com>;
Date: Sat, Aug 29, 2020 04:52 PM
To: "Abdullah Abro"<abroabdullah@gmail.com>;
Cc: "selina"<selina@nbpharm.com>; "shirlyran"<shirlyran@nbpharm.com>; "Obaidullah Malik"<obaiddr@yahoo.com>;
Subject: Re:Confirmation of Authenticity of Stability Data

Aug.31, 2020

STATEMENT

To whom it may concern,

Hereby, we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg:	19277800	Oct 20, 2017
	Each ampoule (2mL) contains:	19277801	Oct 21, 2017
	Irinotecan hydrochloride trihydrate……40mg	19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg:	19277803	Oct 23, 2017
	Each ampoule (5mL) contains:	19277804	Oct 24, 2017
	Irinotecan hydrochloride trihydrate……100mg	19277805	Oct 25, 2017

Sincerely yours,
Quality Management Department

For and on behalf of
Cisen Pharmaceutical Co. Ltd.

2316.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 40mg
	Composition	Each ampoule (2ml) contains: Irinotecan…… 40mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK)

	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066186)
	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/62246) issued by Jining Food and Drug Administration valid till 14/12/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted (dated 15th August 2017, and after that on dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (2ml) contains: Irinotecan…… 40mg CoPP valid till 14-12-2017 Copy of valid DSL Composition different from reference?	
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (19277800 Mfg date: Oct 20, 2017, 19277801 Mfg date: Oct 21, 2017, 19277802 Mfg Date: Oct 22, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 14/12/2017.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2317.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021

	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 100mg
	Composition	Each ampoule (5ml) contains: Irinotecan…… 100mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066187)
	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/47074) issued by Jining Food and Drug Administration valid till 16/09/2017 **declaring the free sale of applied product and GMP compliant status of the manufacturer.**
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted data dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (5ml) contains: Irinotecan…… 100mg CoPP valid till 16-09-2017	
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg)	

	Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (1977803 Mfg date: Oct 23, 2017, 19277804 Mfg date: Oct 24, 2017, 19277805 Mfg Date: Oct 25, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 16/09/2017.
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**

c. New cases (Import) Veterinary

2318.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Drug Sale License	M/s Geevet International Naz Medicine Market Namak Mandi Peshawar Whole sale / distributor Valid till 01/01/2022.
	Name and address of manufacturer	**Manufacturer and MAH:** M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27773 Dated 13-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 13-08-2018
	Brand Name +Dosage Form + Strength	Lincocid Gold soluble powder
	Composition	Each gram contains: Spectinomycin base…..444mg Lincomycin base……..222mg
	Finished Product Specification	Chinese Pharmacopoeia
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1kg, 500gm, 250gm
	Me-too status	LINCO-S 100 W/S POWDER by M/s Attabak, Reg. No. 062169
	Stability studies	Firm has submitted long term (24 months) at 30°C 65% RH & accelerated (06 months) stability data at 40°C, 75% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (Certificate#. 05019)** Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023 Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2319.	Name and address of Applicant	M/s Qualivet Pharma, No.5/15, Ground Floor, Survey No.79, Golden town, Karachi.

	Detail of Drug Sale License	**Address:** M/s Qualivet Pharma, H.No. 5/15 Groud floor, survey no.79 golden town Karachi. **Validity:** 26-11-2019 **Status:** License to sell, stock & exhibit for sale, distribute and sell drugs by way of WHOLE SALE by manufacturer, importer or intender.
	Name and address of manufacturer	M/s Laboratory Karizoo SA, , Mas Pujades, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain.
	Name and address of marketing authorization holder	M/s Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 32632 Dated 01-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 01-10-2018
	Brand Name +Dosage Form + Strength	LEVOFLOK 100mb/ml Oral Solution
	Composition	Each ml contains: Enrofloxacin……..100mg
	Finished Product Specification	Mfg specs
	Pharmacological Group	Abtibacterial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	250ml, 1Litre, 5Litre
	International availability	Available in Spain for free sale as per CoPP
	Me-too status	ROXIN 10% ORAL SOLUTION by M/s M&H PHARMACEUTICALS LAHORE (Imported) Reg. No. 015495
	Detail of certificates attached	**Original Legalized CoPP:** **Certificate No:** Nil **Certifying Authority:** Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Issue Date:** 10/05/2018 **Free sale in exporting country:** Yes **Applicant of certificate:** Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain. **GMP:** • **Original legalized GMP Certificate** **Certificate no.** ES/135HV/19 **Manufacturer Address:** M/s Laboratory Karizoo SA, Mas Pujades, 5-10, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain. **Issued by:** Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Status:** valid till 23/04/2022
	Remarks of the Evaluator:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Moreover the applicant will provide the valid copy of Drug sale License.	
2320.	**Name and address of Applicant**	M/s Hassan Brothers House No. 318 St. # 6 Fatehabad Sharqi, Satiana Road Faisalabad
	Detail of Drug Sale License	M/s Hassan Brothers Ground floor P. 318 St. # 6 Mohallah Fateh abad Sharqi, Satiana Road Faisalabad License to sell drugs as a distributor No: 0011000 0001570 valid upto *29-March-2020. *The firm has submitted the receipt for renewal of DSL dated 24/06/2020.
	Product License Holder & Manufacturer	Head office: M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea

		Factory: M/s Samyang Anipharm co. Ltd. 35, Songseon-ro 265 beon-gil, Pocheon-si, Gyconggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 42885 Dated 17-12-2018
	Fee including differential fee	Rs. 100,000/- Dated 17-12-2018
	Brand Name +Dosage Form + Strength	FLOCOL-200 SOLUTION
	Composition	Each ml contains: Florfenicol….200mg
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Pack size & Demanded Price	500ml, 1L, 2.5L & 5L
	International availability	Korea
	Me-too status	TEMPRO-20% LIQUID by M/s Ras Pharma, Reg. No. 96838
	Stability studies	Real Time data for 24 months Accelerated data for 6 months as per Zone-IVA submitted.
	Detail of certificates attached	• Original Legalized FSC (Certificate#. M1813617) issued on 02-10-2018 by Animal and Plant Quarantine Agency Korea declaring the free sale of applied product in country of origin Korea. • Original Legalized GMP issued by Animal and Plant Quarantine Agency Korea dated 02-10-2018. • Original sole agency agreement is submitted. M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea appointed M/s Hasssan Brothers Faisalabad as Distributor for Pakistan for the applied product.
	Remarks of the Evaluator.	
	Decision: Approved as per policy for inspection of manufacturer abroad.	
2321.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 25112 Dated 19-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-07-2018
	Brand Name +Dosage Form + Strength	Bravecto 1000mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product certificate no. 05/17/110419 issued by EMA on 28/06/2017,

		the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	The submitted stability data contains the results of only initial time point. Submit 06 months accelerated stability and 24 months real time stability study data according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2322.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21640 Dated 20-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 20-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 112.5mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……112.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.**	

	• **Detail of pack size of the applied product.**	
2323.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21052 Dated 12-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 08-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 250mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2324.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 17307 Dated 10-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-05-2018
	Brand Name +Dosage Form + Strength	Bravecto 500mg Chewable tablets for dogs

	Composition	Each Chewable table contains: Fluralaner……500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product. Me-too status of the product
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2325.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9004 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Reefmox oral powder 50%
	Composition	Each gram contains: Amoxicillin trihydrate…… 500mg
	Finished Product Specification	
	Pharmacological Group	Antiobiotic
	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00079. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.

	Remarks of the Evaluator.	Provide product specific sole agency agreement. Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decsion: Deferred for the following: • **Provide product specific sole agency agreement.** • **Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2326.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9002 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Neoreef 500 oral powder
	Composition	Each gram contains: Neomycin sulphate…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic
	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00078. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required.

		Provide valid copy of Drug Sale license.
	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license**.	
2327.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9003 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Reedox 500 oral powder
	Composition	Each gram contains: Doxycycline HCl…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00077. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2328.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.

	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain **Exporter:** MPA Vetrinary Medicines and Additives S.L. C/Mogoda, 16-18 Pol. Ind. Can Salvatella. Barbera del Valles. Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 4657 Dated 01/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Linesvall 150mg/ml solution for injection
	Composition	Each ml contains: Lincomycin as hydrochloride……..50mg Spectinomycin as sulphate tetrahydrate…….100mg
	Finished Product Specification	In House
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml vial, Price decontrolled
	Me-too status	BIO-LINCO-S INJECTION. 200/50mg per ml by M/s International chempharma Reg. No. 39967
	Stability studies	36 months data according to the conditions of zone IV-A of 3 batches is submitted. Accelerated data is not submitted.
	Detail of certificates attached	Legalized Free sale certificate issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2329.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A

	Diary No. & Date of R& I	Dy. No 4658 Dated 01/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Tilovall 200mg/ml solution for injection
	Composition	Each ml contains: Tylosin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Pack size & Demanded Price	Price decontrolled, 100ml vial
	Me-too status	BILOSIN 200MG/ML SOLUTION FOR INJECTION by M/s Binsadiq International, Reg. no. 84841
	Stability studies	24 months real time, 06 months accelerated stability
	Detail of certificates attached	Legalized Free sale certificate for Tilovall 200mg/ml issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2330.	Name and address of Applicant	M/s ZS Biotech Animal Health Company. 50-C Madina Block Awan Town Multan Road, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Farmabse Saude Animal Ltda Av. Emilio Marconato, nº 1000-Galpao A-Jaguariuna (SP) Brazil.
	Name of exporting country	brazil
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 2972 Dated 23/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 23/01/2019
	Brand Name +Dosage Form + Strength	Farmadox 50 oral powder
	Composition	Each 100 gram contains: Doxycycline hyclate……. 50gm
	Finished Product Specification	
	Pharmacological Group	tetracycline
	Shelf life	2 years
	Pack size & Demanded Price	200gm & 25kg, price decontrolled
	Me-too status	
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Original and legalized free sale certificate is submitted while legalized free sale with English translation is required. As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify. Submit 06 months accelerated stability studies of 03 batches.

		Valid copy of Drug Sale License is required. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following; • **Original and legalized free sale certificate is submitted while legalized free sale with English translation is required.** • **As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify.** • **Submit 06 months accelerated stability studies of 03 batches.** • **Valid copy of Drug Sale License is required.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2331.	Name and address of Applicant	M/s Orient Animal Health (pvt) ltd. Commercial #6, Block-A, 1st floor, Kazimabad, Near Masjid e Hira, Model Colony, Karachi.
	Detail of Drug Sale License	Drug License by way of wholesale Address: Orient Animal Health (PVT) LTD. Comm-6 Block-A Ist floor Kazimabad, Model Colony Karachi. Godwon: Ground floor C-14 Block-A Kazimabad Model Colony Karachi. Validity: 22/10/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Univet Ltd., Tullyvin, Cootehill, County Cavan, H16 T183 , Ireland.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1689 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Solu-Flox 100mg/ml solution for use in drinking water
	Composition	Each ml contains: Enrofloxacin…… 100mg
	Finished Product Specification	In House
	Pharmacological Group	Anti bacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml, 1 litre, 5 litre, price decontrolled
	Me-too status	ENROFLOX SOLUTION (10gm/100ml) by M/s Biorex, Reg. No. 031528
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate. Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.
	Decision: Deferred for the following: • **Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate.** • **Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A.**	

	• **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.**	
2332.	Name and address of Applicant	M/s HPI Pharma, Bao wala Opposite truck stand gate no. 2 Rasheed Abad, Jhang Road Faisalabad.
	Detail of Drug Sale License	Drug License by way of wholesale Address: HPI Pharma, Ground floor P-171 Medol Town-B, District Faisalabad. Karachi. Validity: 08/08/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Industrial Veterinaria, S.A Esmeralda 19, 08950 Espulgues de Llobregat Barcelona, Spain.
	Name of exporting country	spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5170-B Dated 06/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 06/02/2019
	Brand Name +Dosage Form + Strength	Pluscolan concentrate for oral solution
	Composition	Each ml contaions: Colistin sulfate……..5,000,000 IU
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Pack size & Demanded Price	100ml, 1litre, 5litre, price decontrolled
	Me-too status	
	Stability studies	24 moths real time and 06 months accelerated of 3 batches as per ZONE IV-A.
	Detail of certificates attached	Original legalized free sale certificate issued on 06/07/2018, the product is freely sold in exporting country and the manufacturer conforms to WHO-GMP as per the certificate.
	Remarks of the Evaluator.	Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

d. Case no. 4: Deferred cases (Import) Veterinary

2333.	**Name and address of Applicant**	**M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore**
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria

		(QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Vetmulin 450mg/g Water soluble granules
	Diary No. Date of R& I & fee	Dy No. 336 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Tiamulin hydrogen fumarate ……450 mg
	Target Specie	Chicken, Turkey
	Pharmacological Group	ATC Vet Code: QJ01XQ01 Antibacterials for systemic use, Pleuromutilins
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years (supported by accelerated and real time stability data)
	Pack size & Demanded Price	1 kg sachet
	Approval status of product in Reference Regulatory Authorities.	Vetmulin (Denmark Approved) HPRA Approved
	Me-too status	006846 TIAMUTIN 45% HILTON KARACHI
	CoPP/GMP status	**Original, legalized certificate of origin and free sale** issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale **Copy of GMP certificate** (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food **Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria**
	Remarks of the Evaluator.	**Withdrawal Period:** Chickens Meat and offal: 3 days Eggs: Zero days Turkeys Meat and offal: 5 days ● The address of manufacturing site on GMP certificate is "39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria" which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag.

	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate. Decision of 285th meeting of Registration Board: "Deferred for above clarifications" Now the firm has submitted the following documents: d. Vetmulin 450mg/g It is a 1kg sachet. e. Original Legalized CoPP (Certificate#. BG 6/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria) f. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2334.	**Name and address of Applicant**	M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) **48 Vasil Petleshkov Str Peshtera 4550,Bulgaria** **(Manufactures)**
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Tilmovet 250mg/ml Concentrate for oral solution

	Diary No. Date of R& I & fee	Dy No. 337 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each ml contains Tilmicosin ……250 mg
	Target Specie	Chicken (Broiler, pullets), Turkey and Calves
	Pharmacological Group	Antimicrobials for systemic use, macrolides ATC vet code: QJ01FA91
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Pack size & Demanded Price	960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper-evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET. 60 mL PET vials with closure of PET/PE
	Approval status of product in Reference Regulatory Authorities.	HPRA Approved
	Me-too status	044909 HICOS 250 ORAL SOLUTION HILTON PHARMA (PVT) LTD., KARACHI.
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale Copy of GMP certificate (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate
	Remarks of the Evaluator.	Withdrawal Period: Calves: 42 days. Chickens: 12 days Turkeys: 19 days Eggs: Not authorized for use in birds producing eggs for human consumption. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD.
	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder **mentioned on Form 5A. Clarification is required.**

	Fresh Evaluation: a. **Clarification for type of container whether you have applied for sachet or bag.** 960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET.60 mL PET vials with closure of PET/PE. b. **The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence.** **(QC and Batch Release+Headquarter)** Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria **(Manufactures)** 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. **The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.** Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate. **Decision of 285th meeting of Registration Board:** "Deferred for above clarifications" Now the firm has submitted the following documents: d. Tilmovet 250mg/ml concentrate for oral solution is packed in 3 container types and sizes: High density polyethylene (HDPE) bottles of 960ml with vertically see-through bar and a graduated scale provided with white tamper evident closure made of PP with white foamed sealing disk. High-density polyethylene (HDPE) bottles of 240ml with a closure made of polyethylene terephthalate (PET). Polyethylene terephthalate (PET) vials of 60ml with a closure made of polyethylene terephthalate/polyethylene (PET/PE). **(**Provided stability data is of only 240ml bottle) e. Original Legalized CoPP (Certificate#. BG 7/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria) f. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2335.	**Name address of Applicant**	M/s Saadat International, 117 Habitat Flat Shadman II Jail Road Lahore
	Drug Sale License	**Address**: 117 Habitat Flat Shadman II Jail Road Lahore Lahore **Validity:** 12-06-2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria

	Brand Name +Dosage Form + Strength	HydroDoxx 500mg/g Powder for use in drinking water
	Diary No. Date of R& I & fee	Dy No. 335 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Doxycycline (as hyclate) ……500 mg
	Pharmacological Group	ATC Vet Code: QJ01AA02.: Antibacterial for systemic use; tetracyclines Tetracycline
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Target Specie	Chicken Broiler
	Shelf life	3 years (supported by accelerated and real time stability data) Shelf-life of the veterinary medicinal product as packaged for sale: 36 months(HPRA)
	Pack size & Demanded Price	1kg sachet
	Approval status of product in Reference Regulatory Authorities.	Ireland Approved HPRA
	Me-too status	023470 Doxyveto- 50 S Soluble Powder Vmd Pakistan Rawalpindi
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale. Copy of GMP certificate (No. 64/2017/GMP) issued on 01-13-2017 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria
	Remarks of the Evaluator.	Withdrawal Period: Meat and offal: Chicken : 6 days Not authorized for use in laying birds producing eggs for human consumption Do not use within 4 weeks of onset of the laying period. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag
	(M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP

		certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale Certificate.	
	Decision of 285th meeting of RB: Deferred for above clarifications Now the firm has submitted the following documents: d. It is a 1kg sachet e. **Original Legalized CoPP (Certificate#. BG 5/2019)** issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company**, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria**. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: **39, Petar Rakov Street,** 4550 Peshtera, Bulgaria while address of manufacturing site is **48 vasil Petleshkov street**, Peshtera 4550, Bulgaria) f. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2336.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26825 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	COLMYC 20% Oral solution for administration in drinking water
	Composition	Each ml contains: Enrofloxacin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	3 years store below 30^0C
	Demanded Price	Decontrolled

	Pack size	500ml, 1L,5L
	Me-too status	EL-FLOXACIN LIQUID of M/s ELKO ORGANISATION,
	Stability studies	Firm has submitted long term (36 months) at 30ºC 75±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 14th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	Applied product is **Suspension as per USP monograph but applied product is solution dosage form**.
	Decision of 292nd meeting of Registration Board: Deferred for following: Applied product is suspension as per USP monograph, but applicant apply solution dosage form. M/s Poul Med submitted that the European Pharmacopoeia monograph number 2229 for Enrofloxacin (Enrofloxacin for veterinary use) is the only monograph available for Enrofloxacin in the European Pharmacopoeia. It describes the tests and specifications that the raw material (enrofloxacin) must follow to comply with the European Pharmacopoeia standards. It does not state that it is for suspension product forms only. Decision of 293rd meeting: Registration Board deferred the application for dosage form clarification. Submission by the firm: The firm has submitted that the dosage form of the applied product is Oral Solution while in USP describes the monograph for Oral Suspension. The firm has requested for grant of registration with innovator's specifications. Moreover, the firm has submitted fee Rs. 5,000/- with the reply (challan number 0539489 dated 22/04/2020). **Decision: Deferred for confirmation of composition of formulation in the database of importing country.**	

Case No. 5: Import cases (Human) Form 5F

2337.	**Name, address of Applicant / Importer**	**M/s** Gene Tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi
	Details of Drug Sale License of importer	**License No:** 10725 **Address:** Gene-tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi **Validity: ***15-August-2020 **Status:** Drug License By way of Wholesale *The firm has submitted receipt for renewal of DSL dated 24/05/2020.
	Name and address of marketing authorization holder (abroad)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name, address of manufacturer(s)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Legalized CoPP (Certificate Ref. 665/5405)** 20-04-2019 by Ministry of Health and Medical Education declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Product specific sole agency agreement is

		submitted.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	Alvocade Single use vial containing 3.5mg powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Bortezomib powder….3.5mg
	Pharmaceutical form of applied drug	Powder for Injection IV/Sc
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-House
	Proposed Pack size	1 vial box
	Proposed unit price	73.2 Dollars
	The status in reference regulatory authorities	Bortezomib 3.5 mg powder for solution for injection (UK)
	For generic drugs (me-too status)	Egybort injection by M/s Revive Pharma, Reg. No. 090738
	Module-II (Quality Overall Summary)	The submitted QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Laurus Labs Limited Plot no.21 Jawaharlal Nehru Pharma City, Parawada Visakhapatanma 531021 Andra Pradesh India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted. Real time at -20^{o}C±5^{o}C for 12 months Accelerated study at 5^{o}C±3^{o}C for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted comparative table summarizing results of all physico-chemical tests performed on 5 batches of applied product and one batch of the reference product i.e. Omnipaque injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 12 months.
	Evaluation by PEC:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2338.	**Name, address of Applicant / Importer**	**M/s** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad
	Details of Drug Sale License of importer	**License No:** DSL-002-ICT/2013 **Address:** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad **Address of Godown:** Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. **Validity:** 30/01/2022 **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	**Manufacturing site:** **Site responsible for batch release, primary and secondary packaging:** M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original Legalized CoPP (Certificate#. 2019-D1-0700) by Ministry of Food and Drug Safety declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s ILDONG Pharmaceutical co., ltd. Korea. Issued date: Mar. 15, 2019
	Details of letter of authorization / sole agency agreement	Authorization letter by manufacturer M/s ILDONG Pharmaceutical co., ltd. In the name of importer M/s Amgomed registration, sale and distribution in Pakistan.
	Status of the applicant	☐ Manufacturer

		☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	SPECSSA Tablet 250mg (Gefitinib)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Gefitinib……..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anticaner
	Reference to Finished product specifications	In house
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**IRESSA of USFDA**
	For generic drugs (me-too status)	Gefticip 250mg Tablet of M/s AJMs
	Module-II (Quality Overall Summary)	Submitted. The QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Mac chem Products (India) Pvt. Ltd. N-211/2/10. Tarapur MIDC.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time at 30°C±2°C & 65%RH±5% of 3 batches for 24 months Accelerated at 40°C±2°C & 65%RH±5% of 3 batches for 24 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVC blister and hard foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 36 months.
	Evaluation by PEC:	
	Decsion: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2339.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16455 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 5ml contains: Paclitaxel……30mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	antineoplastic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Paclitaxel Injection 30mg/5Ml of M/s Innopharm Karachi
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25°C±2°C 60%±5% RH) 24 months and Accelerated study (40°C±2°C 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted pharmaceutical equivalence against the innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC-I:		
Decision: Deferred for clarification regarding storage conditions of stability study data of finished product which is not as per Zone IVA.		
2340.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging

		☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16457 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 16.7ml contains: Paclitaxel……100mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Ebetaxel 100mg/16.7Ml Injection M/s Bio Pharma
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		

2341.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16456 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 50ml contains: Paclitaxel……300mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	DRIFEN 300MG INJECTABLE SOLUTION M/s Haji Medicine
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		
2342.	Name, address of Applicant / Importer	M/s Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	Drug License by the way of Wholesale License No: 0865

		Address: Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. Validity: 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Free sale certificate no. 2017-019 issued by Neijiang Bureau of Ministry of Commerce of the people's republic of China on 27/07/2017. Eudra GMDP status checked from web dated 10-07-2019 show that competent authority of the UK confirms the following manufacturer M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China has been inspected dated 21/08/2017, it is considered that it complies with the principle and guideline of GMP laid down in Directive 2003/EC.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 3687 Dated 16-04-2019
	Details of fee submitted	Rs. 100,000/- Dated 16-04-2019
	The proposed proprietary name / brand name	Azacitidine Seacross powder for suspension for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Azacitidine……..100mg
	Pharmaceutical form of applied drug	Powder for suspension for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product	USP

	specifications	
	Proposed Pack size	1's 30ml glass Vial
	Proposed unit price	Price as per SRO
	The status in reference regulatory authorities	VIDAZA of Baxter Oncology GmbH 33790 Halle/Westfalen Germany
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25°C±2°C 60%±5% RH) 24 months and Accelerated study (40°C±2°C 75%±5% RH) 6 months of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted against the innovator product VIDAZA® by M/s Colgene. As the product is intended to be administered Sc, therefore In-vitro dissolution testing at 37°C against the innovator product is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (30°C±2°C 65%±5% RH) 36 months and Accelerated study (40°C±2°C 75%±5% RH) 6 months of 3 batches.
Evaluation by PEC: FSC issuing authority Neijiang Bureau of Ministry of Commerce of the people's republic of China which is not concern regulatory authority i.e. China Food & Drug Administration.		
Decision: Deferred for issuance of CoPP from relevant regulatory authority.		
2343.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor

		*the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Original Legalized CoPP (Certificate#. 2018-0070)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22424 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 50mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..50mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 50 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan
	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 50MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.

	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25ºC for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: Submitted comparative dissolution profile of applied Neolymin 50mg Soft Gelatin Capsule with Neoral 25mg, Justify. (The firm has stated that the formulation of cyclosporine capsule 25mg and 50mg is proportional and the manufacturing process is the same.)		
Decision: The Board deferred the case for submission of comparative dissolution profile of the applied product against the reference product of the same strength that is 50mg.		
2344.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor *the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan,

		Guangdong Province China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Original Legalized CoPP (Certificate#. 2018-0069)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer..
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22423 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 25mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..25mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 25 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan
	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 25MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25°C for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: The seal of the submitted CoPP is not intact.		
Decision: Approved as per Import Policy for finished drugs. Firm will submit valid CoPP for further processing of case.		
2345.	Name, address of Applicant / Importer	**M/s** M/s OBS Pakistan Pvt. Ltd., C-14, Manghopir Road, S.I.T.E. Karachi
	Details of Drug Sale License of importer	**License No:** 0950 **Address:** OBS Pakistan PVt LTD Plot No. C-14, Manghopir Road Site area Karachi. **Validity**26-03-2021 **Status:** Drug License by Way of Wholesale
	Name and address of marketing authorization holder (abroad)	**Product License Holder:** Merck Sharp and Dome B.V., Waarderwg 39, 2031 BN Haarlem, the Netherlands.
	Name, address of manufacturer(s)	**Manufactured by**: Steri Pharma, LLC 429S.West street Syracuse, NY 13202, USA **Released By:** Laboratoires Merck Sharp & Dohme Chibret, Route de Marsat-Riom, 63963 Clermont Ferrand Cedex 9, France
	Name of exporting country	Netherland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2FM2-4328) by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer. Certificate Expiration Date: June 24, 2021.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted. MSD authorizes M/s OBS Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21535 Dated 22-10-2019
	Details of fee submitted	(Rs. 100,000/- Dated 22-10-2019)
	The proposed proprietary name / brand name	Zerbaxa, Powder for concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftolozane …1gm (eq. to 1.147g of ceftolozane sulfate) Tazobactam… 0.5g (eq. to 0.537g of tazobactam sodium)
	Pharmaceutical form of applied drug	Powder for concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	In-house
	Proposed Pack size	10's vials
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Ceftolozane: M/s Acs Dobfar, S.p.A (ACSD4) via Marzabotto, 1,7/9 20871 vimercate (MB) Italy. Tazobactam sodium: M/s Qilu Tianhe Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, 250105 Jinan, Shandong Province, P.R. of China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 5±3^{0}C and 6 months at 25^{0}C±60%RH for three batches.
Remarks of Evaluator-I: QOS of module 2 is complete but not as per WHO/Form-5F format. The firm has submitted that the name of legal entity of drug substance manufacturer (Tazobactam Sodium) has been changed from "Qilu Tianhe Pharmacetuical Co., Ltd. to "Shandong Anxin Pharmacetuical Co., Ltd. The firm has stated that the manufacturing site is not changed.Valid GMP of the manufacturer mentioning the changed name and address along with the old name and address of the API manufacturer (certificate no. IT/E/API/04/2020, issued on the basis of inspection conducted on 18-09-2019) is submitted along with the reply. Moreover, updated relevant section (2.3.s.2.1) is submitted as well. Name and address: M/s Shandong Anxin Pharmaceutical Co., Ltd (formerly Qilu Tianhe Pharmaceutical Co., Ltd) No. 10678 Wenliang Road, Dongja town, Licheng District (former No. 849 Dongja town, lichen District, Jinan Shandong, 250105, China.		
Decision: Deferred for submission of complete S part of module 2 and 3 of CTD.		
2346.	Name, address of Applicant / Importer	**M/s** Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi
	Details of Drug Sale License of importer	**Address:** Timax Life Scineces Pvt. Ltd. M-1, Fl-37, Block-B, Gulshan e Jamal Karachi **Validity:** 05/03/2021
	Name and address of marketing authorization holder (abroad)	M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570 Tandogan-ANKARA/ TURKEY
	Name, address of manufacturer(s)	M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2018/2468) issued on 28-06-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey valid until 28/06/2020.
	Details of letter of authorization / sole agency agreement	Original legalized Authorization letter from Product License Holder: M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570 Tandogan-ANKARA/ TURKEY in the name of importer M/s Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi for product MRSACIN-50mg containing lyophilized powder for IV infusion is submitted
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 42062 Dated 07-12-2018
	Details of fee submitted	(Rs. 100,000/- Dated 07-12-201)
	The proposed proprietary name / brand name	MRSACIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Lyophilized tigecycline…..50mg
	Pharmaceutical form of applied drug	Lyophilized powder for solution for IV infusion
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil 50 mg powder for solution for infusion (Belgium)
	For generic drugs (me-too status)	Tygatec 50mg Injection of M/s Safe Pharmaceuticals (Pvt) Ltd. Karachi
	Module-II (Quality Overall Summary)	submitted
	Name, address of drug substance manufacturer	M/s UNIMARK REMEDIES LIMITED 501, 5th Floor, E-Wing, Sky Park CHS Ltd., MMRDA District Centre, Oshiwara Garden Road, Off. S.V. Road, Goregaon (West) Mumbai India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted real time stability study data 25°C±2 and 60%±5 for 2 years and accelerated at 40°C±2 and 75%±5.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	The firm has submitted real time stability study data 25°C±2 and 60%±5.
Remarks of Evaluator-I: Stability study data (Real time + Accelerated) according to the conditions of Zone-IVA required.		
Decision: Deferred for submission of real time and accelerated stability data of 03 batches according to the conditions of zone IV-A.		

Case no.6: Deferred cases (import) submitted on Form 5F
2347. Nab-Xelpac Injection (Lyophilized Powder) applied by M/s Himmel Pharmaceuticals (Pvt.) Ltd Lahore

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 26966 Dated 13-12-2019 PKR: 50,000/- dated 19-03-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2	Name, address and contact details of Manufacturing site. Product License Holder & Manufacturer: M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** License to Sell drugs as a Distributor No: 0011000 0001520 valid upto 06-Feb-2020
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Nanoparticle Albumin bound Paclitaxel USP
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Nanoparticle Albumin bound Paclitaxel USP …..100mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Nab-Xelpac Injection (Lyophilized Powder)
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API)

		Antineoplastic agents
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration IV
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price ONCOTAXEL 100MG INJECTION of M/S. PHARMEVO (PRIVATE) LIMITED,
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Abraxane 5 mg/ml powder for suspension for infusion (Netherlands)
	1.5.10	Dosage form of applied drug Injection (Lyophilized Powder) : 100mg
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.

	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. DA/6-110/2016/3677)** issued on 18-02-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited. • Copy of Product specific sole agency agreement is submitted.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION

	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	

	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Decision of 293rd meeting: Deferred for submission of all commitments of module 1. Evaluation by PEC: The firm has submitted all the commitments of module I. **Decision: Approved as per Policy for inspection of Manufacturer abroad.**		

Deferred cases of COVID-19

Sr. No.	Applicant	Brand name	Composition	Dy No./fee/ date/ form	Pack size and price	GMP status	**Previous decision**
2348.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepure road Lahore	Ajicin 200mg/ 5ml for Suspension	Each 5ml reconstituted Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin…200mg	Dy.No. 12453 dated 03/06/2020Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	M/s Novamed: 22-1-2019 Good level of compliance with GMP.	**Deferred in 295th meeting for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing**

Submission by the firm:
The firm has submitted the following;

- Original contract agreement with M/s Novamed Pharma.
- No products are being manufactured on contract basis for M/s Cunningham Pharma.
- Copy of GMP certificate dated 19/04/2019 issue don the basis of inspection conducted on 01/04/2019.
- M/s Cunningham pharma has 7 approved sections.
- The firm does not have the relevant section.

Decision: Approved with USP specifications.

2349.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	Citaquine DS Tablet	Each Film Coated Tablet contains: Chloroquine phosphate……..500mg	Dy.No. 9126 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	30,000/- fee alongwith Fom-5D is required.	**Deferred in 295th meeting for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**

Submission by the firm:
The firm has submitted Form 5D and Differential fee of Rs. 30,000/- vide challan number 0792484 dated 09/06/2020.
GMP inspection dated 13-11-2019 shows that the firm was allowed resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections.

a- Sterile Section-I (General Injection)
b- Sterile Section-III (Hormonal Injection).

Decision: Approved with USP specifications.

2350.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Lopvir 200mg/ 50mg Tablet	Each Tablet Contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 9318 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5D	As per SRO	GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **submission of requisite fee for revision of formulation as per the reference product.**

Submission by the firm:
The firm has submitted;

- Fee of Rs, 5,000/- vide challan number 2039502 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following;
  Each film coated tablet contains:
  Lopinavir…..200mg
  Ritonavir…...50mg
- No product is being manufactured for M/s CSH Pharma on contract basis.
- Inspection report dated 04/05/2020, satisfactory level of GMP compliance.
- The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012.

Decision: Approved with USP specifications.

2351.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Hydroxy Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9315 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Deferred in 295th meeting for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **Submission of requisite fee for revision of formulation as per the reference product.**
Submission by the firm: The firm has submitted; • Fee of Rs, 5,000/- vide challan number 2039501 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following; Each film coated tablet contains: Hydroxychloroquine sulfate…200mg • No product is being manufactured for M/s CSH Pharma on contract basis. • Inspection report dated 04/05/2020, satisfactory level of GMP compliance. • The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012. **Decision: Approved with USP specifications.**							
2352.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Ostar 75mg Capsule	Each capsule contains: Oseltamivir as phosphate…….75 mg	Dy.No. 9316 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Registration Board referred in 295th meeting the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
Submission by the firm: The firm has submitted; • No product is being manufactured for M/s CSH Pharma on contract basis. • Inspection report dated 04/05/2020, satisfactory level of GMP compliance. • The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012. **Decision: Approved with USP specifications.**							
2353.	Deleted due to duplication						
2354.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory	Chloquine Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 7779 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption	**Deferred in 295th meeting for submission of Form 5D along with the**

	Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi					of production Form 5D along with differential fee of Rs. 30,000/- is required..	**submission of Differential fee of Rs. 30,000/-**
Submission by the firm: The firm has submitted differential fee of Rs. 30,000/- vide challan number 2025155 dated 06/05/2020 along with Form 5D. **Decision: Approved with USP specifications.**							
2355.	M/s Maple Pharmaceuticals Pvt Ltd Plot No.147, Sector 23, Korangi Industrial Area, Karachi	C-Sure Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7258 dated 14/04/2020Rs. 20,000/- dated 14-04-2020 Form 5		GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 22/12/2020. The firm has applied for plain tablet while it is approved in reference country as chewable	**Deferred in 295th meeting for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**
Submission by the firm: The firm has revised the formulation from Tablet to Chewable tablet as per the reference product along with method of manufacturing, master formula and other relevant documents with the submission of fee of Rs. 20,000/- vide challan number 2001182 dated 18/08/2020. **Decision: Approved with USP specifications.**							
2356.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Macazit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate.…500mg	Dy.No. 11497 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's as per SRO	03/05/2019 inspection dated. The panel recommended renewal of DML.	**Deferred in 295th meeting for submission of method of manufacturing.**
Submission by the firm: The firm has submitted method of manufacturing for the applied product. **Decision: Approved with USP specifications.**							
2357.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H, Sector 15 Korangi Induatrial Area Karachi	Azax 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate Eq. to Azithromycin……250mg	Dy.No. 11721 dated 21/05/2020Rs. 20,000/- (#1962153) dated 21-05-2020 Form 5	6's as per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.	**Deferred in 295th meeting for updated status of GMP from QA & LT.**
Submission by the firm: The firm has submitted last inspection report dated 09/01/2020, the report concludes that the firm was operating at acceptable level of GMP compliance. **Decision: Approved with USP specifications.**							

New Applications related to COVID-19 (Import)

2358.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 14513 Dated : 23/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 23/06/2020
	Brand Name +Dosage Form + Strength	Oseltamivir Phosphate Capsule 75mg
	Composition	Each capsule contains: Oseltamivir as Phosphate……75mg
	Finished Product Specification	USP
	Pharmacological Group	antiviral
	Shelf life	18 months
	Pack size & Demanded Price	As per SRO
	International availability	Tamiflu 75mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.
	Me-too status	Tamiflu 75mg capsule by M/s Roche.
	Stability studies	Accelerated stability study data of 03 batches for 6 months Real time stability data of 03 batches for 09months is submitted
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-19-01129 **Certified by:** Food and Drug Administration Ministry of Public health **Date of issuance:** 21/08/2019 **Free sale:** yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	Real time stability data is till 9 months,
	Decision: Deferred for confirmation of shelf life as 9 months stability data has been submitted	
2359.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 13657 Dated : 15/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 15/06/2020
	Brand Name +Dosage Form + Strength	Lopinavir/Ritonavir Tablet 200/50mg
	Composition	Each film coated tablet contains: Lopinavir……200mg Ritonavir…….50mg
	Finished Product Specification	USP
	Pharmacological Group	Anti retroviral
	Shelf life	2 years
	Pack size & Demanded Price	Rs. 15,500/- per 120 tablets
	International availability	Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved.
	Me-too status	Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED, Rweg No. 62250
	Stability studies	Accelerated stability study data of 03 bathes for 6 months Real time stability data of 03 batches for 24 months is submitted as per Zone IVA
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-20-00304 **Certified by:** Food and Drug Administrtaion Ministry of Public health **Date of issuance:** 23/04/2020 **Free sale:** Yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

Case no. 01 Review of the previously presented cases

Following application was approved in 286th meeting of Registration Board held on 14th - 16th November, 2018. During subsequent processing of the said case, it has been identified that the evidence of approval of applied formulation i.e., "Each capsule contain Gabapentin …. 60mg" is not verifiable from any of the reference regulatory authorities, rather "Gabapentin 600mg tablet" is approved by US FDA. Hence the case is presented before the Board for re-consideration.

2173.	**Name and address of manufacturer / Applicant**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Brand Name +Dosage Form + Strength	Parkopentin 600mg Capsule
	Composition	Each Capsule Contains: Gabapentin…600mg
	Diary No. Date of R& I & fee	Dy.No 24892 dated 18-07-2018 Rs.20,000/- Dated 16-07-2018
	Pharmacological Group	Anti-convulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per Drap Policy
	Approval status of product in Reference Regulatory Authorities.	**USFDA Approved**

	Me-too status	**Kendis Tablets 600mg Reg # 064838**
	GMP status	The CLB in its 259th meeting held on 29th and 30th March 2018 has considered and approved the grant of DML by way of formulation. d) Tablet (General Section) e) Capsule (General Section) f) Liquid Syrup (General Section)
	Remarks of Evaluator	
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	

Case no. 02 Registration applications for local manufacturing of (Human) drugs

b. New cases

2174.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Merolit 1gm Injection
	Composition	"Each vial contains: Meropenem……1gm"
	Diary No. Date of R& I & fee	Dy. No 16389 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[II]	Initially form has submitted stability study reports for accelerated conditions but now the applicant has requested a sunder: "This is our product Merolit 500mg & 1gm, its me too status is available, we want to withdraw its stability and require normal approval of product."
	Decision: Deferred for consideration as per queue.	
2175.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name + Dosage Form + Strength	Merolit 500mg Injection
	Composition	"Each vial contains: Meropenem…500mg"
	Diary No. Date of R& I & fee	Dy. No 16390 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [II]	
	Decision: Deferred for consideration as per queue.	

b. Deferred cases

2176.	**Name and address of manufacturer / Applicant**	**M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name +Dosage Form + Strength	Zibix 200mg Tablet
	Composition	Each film coated Tablet Contains: Celecoxib……200mg
	Diary No. Date of R& I & fee	Dy.No.16179 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength/dosage form)	Coxia 200 mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Celebrex 200mg capsule" of M/s Upjohn UK Limited approved by MHRA of UK whereas applied formulation is of tablet dosage form. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

2177.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 10mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…10mg Atorvastatin (as calcium trihydrate) …10mg"
	Diary No. Date of R& I & fee	Dy. No 28143 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Combitrol 10/10 tablet by M/s Ferozsons Labs. (Reg#050815)

	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (M-291)	Deferred for confirmation of valid DML status of the firm from Licensing Division.
	Firm's response	Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	
2178.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 5mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…5mg Atorvastatin (as calcium trihydrate) ……10mg"
	Diary No. Date of R& I & fee	Dy. No 28142 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Atease 5+10mg Tablet by M/s PharmEvo (Reg#050559)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Caduet tablet" of M/s PHARMACIA approved by US FDA. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	
2179.	Name and address of manufacturer / Applicant	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg"
	Diary No. Date of R& I & fee	Dy. No 771 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	070493 Prefair 500/15mg M/s Merck, Balochistan

	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.
	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg
	Decision: Approved.	
2180.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/850 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg"
	Diary No. Date of R& I & fee	Dy.No 772 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	076217 Muppet 15mg/850mg Tablet M/s PPP, Karachi.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.
	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg
	Decision: Approved.	
2181	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name+Dosage Form + Strength	Azimed 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin dihydrate…250mg

	Diary No. Date of R& I & fee	Dy.No 44138 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azithromycin 250mg Capsules Unipharma (Pvt) Ltd., 071421
	GMP status	28-09-2017 and good
	Remarks of the Evaluator XIII	• Azithromycin "as" dihydrate is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Previous Decision (M-295)	Deferred for evidence of approval of relevant/required manufacturing facility and revision of formulation as per the innovator / reference product along with submission of fee for revision of formulation.
	Firm's response	• Firm has submitted revised master formulation in line with the reference product i.e., "Each Capsule Contains: Azithromycin as dihydrate……250mg" • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued including the section of "Capsule (general)".
	Decision: Approved as per following composition: "Each Capsule Contains: Azithromycin as dihydrate……250mg"	

2182.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 100mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate……6mcg Budesonide……100mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective beta$_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 100/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 100mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting **(M-289)**. Deferred for confirmation of manufacturing and testing

		facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1).
	Previous decision (M-295):	Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.
2183.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 200mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….200mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications (M-243): • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting (M-289). Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). We have mentioned our drug delivery device as

		CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1)
	Previous decision (295):	Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.
	Firm's response: • As concerned of manufacturing controls for particle size of blend, we will use DPI grade API & lactose (Respitose) as an excepient. Therefore, we do not require spiral jet mill/high shear mixer to fine the material. We have arranged micronized Budesonide, formoterol fumarate and inhalation grade lactose (Respitose SV003) in our proposed formulation. • We are also providing our commitment/undertaking for arrangement/purchase of Spiral Jet Mill/high shear mixer, when our applied products have requirements of particle size reduction in future. • We have separate manufacturing facility for capsules (General) & capsules (steroidal). Our Steroidal capsule manufacturing section is also verified by DRAP Officials during their inspections. We also have separate dispensing booth for dispensing of steroidal API. • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly, we have also included "target delivery dose" in our product specifications.	
	Decision: Registration Board deliberated upon submission of firm and decided as under: **v. Approved the applied product considering the fact that the use of micronized DPI grade APIs does not necessitate the use of Spiral Jet Mill/high shear mixer.** **vi. The firm shall include the test of Aerodynamic particle size distribution" in the finished product specifications to ensure the required particle size of the formulation blend.** **vii. Firm shall use micronized DPI grade excipient for the applied product.** **viii. Registration letter shall be issued with following label claim:** **"Each capsule contains:** **Formoterol Fumarate (micronized) ……. 6mcg** **Budesonide (micronized) ……..… 200mcg"**	
2184.	Name and address of manufacturer / Applicant	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 120 injection
	Composition	Each vial contains: Artesunate ……. 120mg
	Diary No. Date of R& I & fee	Dy. No. 1115, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076073)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.

	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2185.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 30 injection
	Composition	Each vial contains: Artesunate ……. 30mg
	Diary No. Date of R& I & fee	Dy. No. 1118, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076072)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2186.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 60 injection
	Composition	Each vial contains: Artesunate ……. 60 mg
	Diary No. Date of R& I & fee	Dy. No. 1117, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma (Pvt) Ltd. Karachi (Reg#057719)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.

	Decision of 296th meeting: Approved.	
2187.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy. No 28456 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Previous Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019. • Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2188.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy. No 28455 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsule by M/s Getz Pharma (Reg#048725)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019 concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."

	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019. • Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2189.	**Name and address of manufacturer / Applicant**	**M/s. HiMedic Pharmaceutcals (Pvt) Ltd.0 Lahore**
	Brand Name +Dosage Form + Strength	Soclar Drops 50mg/ml
	Composition	Each ml Contains: Cefaclor (as monohydrate)……50mg
	Diary No. Date of R& I & fee	Dy. No.31; 26-07-2016; Rs.20,000/- (26-07-2016)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15ml; Rs. 131.66/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA as suspension dosage form
	Me-too status (with strength and dosage form)	Slate Drops 50mg/ml of M/s SAMI Pharmaceuticals (Reg.# 075939)
	GMP status	Last GMP inspection conducted on 09-08-2018
	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-285)	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 24-01-2020.
	Decision of 296th meeting: Approved with USP specifications.	
2190.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, Pakistan by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 2.25g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…2.0g Tazobactam sodium eq to Tazobactam…0.25g"
	Diary No. Date of R& I & fee	Dy.No 7048 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044142; Tazobact 2.25g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.

	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	
2191.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 4.5g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…4.0g Tazobactam sodium eq to Tazobactam…0.5g"
	Diary No. Date of R& I & fee	Dy.No 7049 dated 19-02-2019 Rs.50,000/- 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044143 Tazobact 4.5g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. Deferred Cases

2192.	**Name and address of Applicant**	**M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan**
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam

		Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • Only brand name has been mentioned without label claim. • The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis. • Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA.

		• The firm submitted Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 26.09.2019.
	Previous decision	The Board in its 293rd meeting deferred the case for or changing the address of applicant in Form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Previous decision (M-295)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Remarks of Evaluator	Following reference of me-too product has been verified: "DOXYSIN WATER SOLUBLE POWDER" of M/s UNIVET PHARMACEUTICALS, RAWALPINDI. (Reg.#033256)
	Decision of 296th meeting: Approved.	

Case no. 04 Registration applications of newly granted DML or New section (Human)

b. New DML /section

M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa, has been granted approval for two new tablet sections in 274th meeting of CLB. Now the firm has applied following products for priority consideration against these two new sections.

2193.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15180: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…5mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)
	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 5mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China		
API Lot No.	ETG20190101		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-001	ERTab-001	ERTab-001
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board.

		Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

2194.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15181: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)

	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 15mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China.		
API Lot No.	ETG20190101		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-004	ERTab-005	ERTab-006
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
5.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance

		with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
6.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
P - PART		
7.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
8.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Registration Board deferred the applications of Ertuvia 5mg Tablet & Ertuvia 15mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
5.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
6.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
P - PART		

	7.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
	8.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

2195.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15183: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia-S 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…….5mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin……100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.

	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China		
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-007	ERTab-008	ERTab-009
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing.

		✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]:		

2196.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15182: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020

	The proposed proprietary name / brand name	**Ertuvia-S 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079
Description of Pack (Container closure system)	Alu-Alu blister in unit carton

Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-010	ERTab-011	ERTab-012
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
6.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
7.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
8.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
		P - PART
9.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP

		chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
10.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Decision: Registration Board deferred the applications of Ertuvia-S 5/100 mg Tablet & Ertuvia-S 15/100 mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
6.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
7.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
8.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.

P - PART		
9.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
10.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Case no. 05 Registration applications of import cases

a. New Cases (Veterinary)

2197	**Name and address of Applicant**	**M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan**
	Detail of Drug Sale License	Address: **M/s Prix Pharmaceutica,** 26 abbot road Lahore (Godown: Plot NO. 5, Pharmacity, 30Km Multan Road Lahore. Validity: 12/06/2022`
	Name and address of manufacturer	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name and address of marketing authorization holder	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name of exporting country	**Italy**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 75 Dated 14-07-2015
	Fee including differential fee	Rs. 50,000/- Dated 10-07-2015
	Brand Name +Dosage Form + Strength	**ZOOCOLAGOGO C.M. Oral Powder**
	Composition	Each 18gm sachet contains: Rhubarb ……. 9gm Boldo leaf …….. 6gm Condurango ……. 2gm Nux vomica ……. 1gm
	Finished Product Specification	Manufacturer's specification
	Pharmacological Group	Products for alimentary tract and metabolism
	Shelf life	5 years
	Demanded Price	Decontrolled
	Pack size	1's
	International availability	Approved by Italy (Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products)
	Me-too status	N/A
	Stability studies	Firm has submitted long term (60 months) at 25+2°C, 60+5%RH & accelerated (06 months) stability data at 40+ 2°C, 75+ 5% RH for three batches.

	Detail of certificates attached	• **Original Legalized CoPP** **Certificate No:** 163/2018/C **Certifying Authority:** Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products **Issue Date:** 19-08-2018 **Free sale in exporting country: Yes** • **GMP of manufacturer:** Yes **GMP Certificate** The GMP certificate (No. NBF/18/2017/V) issued by Ministry of Health - General Directorate of Animal Health and Veterinary Drugs Italy, submitted by the firm and also available at EUDRA GMP database, valid upto 23-02-2020. **Sole Agency Agreement:** Firm has submitted declaration form M/s Fatro S.P.A, Italy wherein M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan has been declared as sole agent in Pakistan for their product "Zoocolagogo C.M. oral powder".
	Remarks of the Evaluator:	
	Decision: Registration Board deferred the case for following: **iv. Opinion from H&OTC division regarding the classification of applied formulation.** **v. Submission of stability data of the applied product as per Zone IV-a conditions.** **vi. Submission of valid legalized GMP certificate of the finished product manufacturer.**	

Case no. 06 Registration applications of drugs for which stability study data is submitted

c. New cases

2198.	**Name and address of manufacturer / Applicant**	**M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Jenta 80mg Injection
	Composition	Each ampoule contains: Gentamicin as sulphate ……. 80mg
	Diary No. Date of R& I & fee	Dy.No.728, 27-7-2016, Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	2 ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL GENTAMICIN 80mg/2mL Injection BP (TGA)
	Me-too status	GENXAT of Surge pharma
		Last GMP Inspection dated 03-04-2019 with conclusive remarks of acceptable cGMP compliance.
	Remarks of Evaluator	
	Decision:	

STABILITY STUDY DATA	
Drug	Jenta 80mg Injection
Name of Manufacturer	M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.
Manufacturer of API	M/s Fujian Fukang Pharmaceutical Co., Ltd., Jiangyin Industrial Estate, Fujian, China
API Lot No.	FG 1608226
Description of Pack	LDPE Ampoule

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,1,3,6 months		
Batch No.	001	002	003
Batch Size	20,000 ampoules	20,000 ampoules	20,000 ampoules
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	20-01-2017	20-01-2017	20-01-2017
No. of Batches	03		
Date of Submission	03-12-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
8.	COA of API	Yes
9.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate (Certificate#FJ20170003) issued by Germany, **valid upto 09-04-2022**
	Protocols followed for conduction of stability study and details of tests.	Yes
10.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
11.	Documents confirming import of API etc.	Copy of ADC attested invoice for Gentamicin sulfate, dated 16-12-2016.
12.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
13.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
14.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

iv. Firm has submitted data for Bio-Assay analysis as per USP monograph.

v. Firm has used LDPE ampoules as primary container closure system for applied formulation which is a semi permeable container. As per ICH guidelines for drug products packaged in semi-permeable containers the testing conditions are:

Study	Storage conditions
Long Term	30°C ± 2°C/35% RH ± 5% RH
Accelerated	40°C ± 2°C/not more than (NMT) 25% RH

vi. The firm has submitted reports of 6 months accelerated & long term stability studies, for all the above three batches of Jenta 80mg injection, the firm has derived water loss rate by applying alternate approach given in the ICH Q1A (R2) guidelines as below:

Batch No.: 001 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3808	0.04	11	3.3821	3.3814	0.06
2	3.3218	3.3208	0.06	12	3.4509	3.4499	0.09
3	3.4285	3.4280	0.03	13	3.4742	3.4737	0.04
4	3.3156	3.3143	0.07	14	3.4351	3.4343	0.07
5	3.3672	3.3661	0.06	15	3.3577	3.3570	0.06
6	3.4264	3.4255	0.05	16	3.4231	3.4222	0.08
7	3.4305	3.4301	0.02	17	3.3688	3.3684	0.04
8	3.3721	3.3706	0.08	18	3.3103	3.3097	0.05
9	3.3985	3.3979	0.03	19	3.3280	3.3277	0.03
10	3.3912	3.3897	0.08	20	3.3902	3.3893	0.08

Batch No.: 001 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3815	3.3790	0.14	11	3.3821	3.3806	0.13
2	3.3218	3.3198	0.11	12	3.4509	3.4496	0.11
3	3.4285	3.4256	0.16	13	3.4742	3.4726	0.14
4	3.3156	3.3134	0.13	14	3.4351	3.4339	0.10
5	3.3672	3.3644	0.16	15	3.3577	3.3563	0.13
6	3.4264	3.4237	0.15	16	3.4231	3.4216	0.13
7	3.4305	3.4277	0.16	17	3.3688	3.3672	0.14
8	3.3721	3.3692	0.16	18	3.3103	3.3084	0.17
9	3.3985	3.3963	0.12	19	3.3280	3.3265	0.14
10	3.3912	3.3892	0.11	20	3.3902	3.3890	0.11

Batch No.: 001 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3780	0.20	11	3.3821	3.3796	0.22
2	3.3218	3.3180	0.22	12	3.4509	3.4486	0.20
3	3.4285	3.4246	0.22	13	3.4742	3.4716	0.22
4	3.3156	3.3124	0.18	14	3.4351	3.4329	0.19
5	3.3672	3.3634	0.21	15	3.3577	3.3553	0.21
6	3.4264	3.4227	0.21	16	3.4231	3.4206	0.22
7	3.4305	3.4257	0.27	17	3.3688	3.3662	0.23
8	3.3721	3.3682	0.22	18	3.3103	3.3074	0.26
9	3.3985	3.3953	0.18	19	3.3280	3.3265	0.14
10	3.3912	3.3877	0.20	20	3.3902	3.3880	0.19

Batch No.: 002 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3942	3.3935	0.04	11	3.3924	3.3917	0.06
2	3.3861	3.3851	0.06	12	3.3891	3.3881	0.09
3	3.4025	3.4020	0.03	13	3.3642	3.3637	0.04
4	3.3814	3.3801	0.07	14	3.3904	3.3896	0.07
5	3.3881	3.3870	0.06	15	3.3891	3.3884	0.06
6	3.3790	3.3781	0.05	16	3.3947	3.3938	0.08
7	3.3953	3.3949	0.02	17	3.3982	3.3978	0.04
8	3.3684	3.3669	0.08	18	3.3862	3.3856	0.05
9	3.3943	3.3937	0.03	19	3.3944	3.3941	0.03
10	3.3769	3.3754	0.08	20	3.3983	3.3974	0.08

Batch No.: 002 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3912	3.3887	0.14	11	3.3924	3.3909	0.13
2	3.3704	3.3684	0.11	12	3.3891	3.3878	0.12
3	3.3845	3.3816	0.16	13	3.3642	3.3626	0.14
4	3.3905	3.3883	0.12	14	3.9904	3.9892	0.09
5	3.3887	3.3859	0.16	15	3.3891	3.3877	0.12
6	3.3781	3.3754	0.15	16	3.3947	3.3932	0.13
7	3.3826	3.3798	0.16	17	3.3982	3.3966	0.14
8	3.3942	3.3913	0.16	18	3.3862	3.3843	0.17
9	3.3807	3.3785	0.12	19	3.3944	3.3929	0.13
10	3.3841	3.3821	0.11	20	3.3983	3.3971	0.11

Batch No.: 002 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3912	3.3877	0.20	11	3.3924	3.3899	0.22
2	3.3704	3.3666	0.21	12	3.3891	3.3868	0.20
3	3.3845	3.3806	0.22	13	3.3642	3.3616	0.23
4	3.3905	3.3875	0.17	14	3.9904	3.9882	0.17
5	3.3887	3.3849	0.21	15	3.3891	3.3867	0.21
6	3.3781	3.3744	0.21	16	3.3947	3.3922	0.22
7	3.3826	3.3787	0.22	17	3.3982	3.3956	0.23
8	3.3942	3.3903	0.22	18	3.3862	3.3842	0.18
9	3.3807	3.3775	0.18	19	3.3944	3.3929	0.13
10	3.3841	3.3806	0.20	20	3.3983	3.3961	0.19

Batch No.: 003 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3845	0.04	11	3.3874	3.3867	0.06
2	3.3945	3.3935	0.06	12	3.3907	3.3897	0.09
3	3.3793	3.3788	0.03	13	3.3791	3.3786	0.04
4	3.3824	3.3811	0.07	14	3.3953	3.3945	0.07
5	3.3948	3.3937	0.06	15	3.3778	3.3771	0.06
6	3.3887	3.3878	0.05	16	3.3827	3.3818	0.08
7	3.3796	3.3792	0.02	17	3.3809	3.3805	0.04
8	3.3821	3.3806	0.08	18	3.3945	3.3939	0.05
9	3.3943	3.3937	0.03	19	3.3824	3.3821	0.03
10	3.3844	3.3829	0.08	20	3.3798	3.3789	0.08

Batch No.: 003 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3852	3.3827	0.14	11	3.3874	3.3859	0.13
2	3.3945	3.3925	0.11	12	3.3907	3.3894	0.12
3	3.3793	3.3764	0.16	13	3.3791	3.3775	0.14
4	3.3824	3.3802	0.12	14	3.3953	3.3941	0.11
5	3.3948	3.3920	0.16	15	3.3778	3.3764	0.12
6	3.3887	3.3860	0.15	16	3.3827	3.3812	0.13
7	3.3796	3.3768	0.16	17	3.3809	3.3793	0.14
8	3.3821	3.3792	0.16	18	3.3945	3.3926	0.17
9	3.3943	3.3921	0.12	19	3.3824	3.3809	0.13
10	3.3844	3.3824	0.11	20	3.3798	3.3786	0.11

Batch No.: 003 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3817	0.20	11	3.3874	3.3849	0.22
2	3.3945	3.3907	0.21	12	3.3907	3.3884	0.20
3	3.3793	3.3754	0.22	13	3.3791	3.3765	0.23
4	3.3824	3.3792	0.18	14	3.3953	3.3931	0.19
5	3.3948	3.3910	0.21	15	3.3778	3.3754	0.21
6	3.3887	3.3850	0.21	16	3.3827	3.3802	0.22
7	3.3796	3.3748	0.27	17	3.3809	3.3783	0.23
8	3.3821	3.3782	0.22	18	3.3945	3.3916	0.26
9	3.3943	3.3911	0.18	19	3.3824	3.3807	0.15
10	3.3844	3.3809	0.20	20	3.3798	3.3776	0.20

Moreover firm has submitted Container Qualification Studies for Low Density Polyethylene (LDPE), as per USP. The submitted studies make following declarations:

- Material pass the test describe in European Pharmacopoeia.
- Material pass the test describe in USP.
- LDPELE6609 PH has FDA drug master file number DMF 17927 (24086 ex Porvoo)
- PCSIR test reports for extractable metals concluded that No Extractable was found in LDPE sample tested as per USP<661.1>.
- Sample analysed as per USP <661.2> and found results within the USP specification.

Decision: Registration Board deliberated the case in detail and considering the submitted stability data "Container qualification studies", the Board decided to approve Jenta 80mg injection (Gentamicin)", of M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.

d. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2199.	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Aglizon 10mg Tablet Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…10mg (In-house specifications)	Form-5D Dy. No: 19554 Dated 30.10.2017 Rs.50,000/- As per SRO (1x10's, 2x10's, 3x10's)	FORXIGA dapagliflozin (as propanediol monohydrate) 10 mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA	
Drug	Aglizon 10mg Tablet
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)

Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4341)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
9.	COA of API	Yes
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion		
20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.

<table>
<tr><td>21.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>➢ <u>Declaration by WIS Pharmtec Co. Ltd, China</u>
The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information.
Batch No.: DGF20180101
Mfg Date: 05.01.2018
➢ <u>Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China</u>
Invoice No. WIS180047
Quantity imported: 0.22 Kg
Date of import: 28.03.2018
ADC Attestation Date: 14.05.2018
Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
Batch No.: DGF20180101</td></tr>
<tr><td>22.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No. The firm submitted that these were in minute quantity and free of cost.</td></tr>
<tr><td>23.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, China for API valid till 18.08.2019, issued by China FDA.</td></tr>
<tr><td>24.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Shangai Pharma Group Changzhou.</td></tr>
<tr><td>25.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of reference standard and impurity A have been submitted.</td></tr>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of three qualified staff involved in product development. One of them is intermediate passed, who is assistant officer production</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
c. Development protocol.
d. Stability Study Protocol.</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>TF001</td><td>05-2018</td><td>1000/992</td></tr>
<tr><td>TF002</td><td>05-2018</td><td>1000/988</td></tr>
<tr><td>TF003</td><td>05-2018</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>TF001</td><td>1000</td><td>992</td><td>480</td></tr>
<tr><td>TF002</td><td>1000</td><td>988</td><td>540</td></tr>
</table></td></tr>
</table>

		TF003	1000	984	540
QA / QC DATA					
31.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Yes			
32.	Method used for analysis of API along with COA.	The firm has applied supplier's method for analysis of API and has submitted their analytical reports, raw data sheets & relevant chromatograms.			
33.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	• The firm has submitted photocopy of Finished Product specification & Test method. • Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)			
34.	Reports of stability studies of API from manufacturer.	The firm has submitted copies of reports of 06 Months Accelerated and 18 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API. **The firm has also submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API, wherein impurity A has not been tested.**			
35.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.			
36.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation.			
37.	Record of comparative dissolution data.	pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8. **Feature** / **Reference product** Brand name: Forxiga Tab. 10mg Batch No.: NX685 Mfg. date: NIL			
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.			

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC: Firm has now submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2200.	M/s Helix Pharma (Pvt.) Ltd.,	Aglizon 5mg Tablet	Form-5D Dy. No: 19540	FORXIGA dapagliflozin (as

	Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…5mg (In-house specifications)	Dated 30.10.2017 Rs.50,000/- (**Duplicate dossier)** As per SRO (1x10's, 2x10's, 3x10's)	propanediol monohydrate) 5mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA			
Drug	Aglizon 5mg Tablet		
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700		
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.		
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4342)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
9.	COA of API	Yes
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.

	manufacturer issued by regulatory authority of country of origin.	
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	➢ **Declaration by WIS Pharmtec Co. Ltd, China** The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information. Batch No.: DGF20180101 Mfg Date: 05.01.2018 ➢ **Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China** Invoice No. WIS180047 Quantity imported: 0.22 Kg Date of import: 28.03.2018 ADC Attestation Date: 14.05.2018 Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China. Batch No.: DGF20180101

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35.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.
36.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation.
37.	Record of comparative dissolution data.	pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8. **Feature** / **Reference product** Brand name: Forxiga Tab. 5mg Batch No.: V832F Mfg. date: NIL
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.

Remarks of Evaluator:

Shortcomings communicated	**Response by the firm**
The testing/analysis method of API is different from that of manufacturer. Justify.	90% Tests inclusive of critical tests, i.e ; Assay, Solubility, Related Substance, Clarity, Water content etc. all are comparative / present in Helix's Testing protocols same as supplier. However, test i.e; particle size is for information only & residual solvent (OVI) would be performed in future once the Gas Chromatography is purchased by Quality Control department. However, as per COA, the firm only performed description, identification water content, residue on ignition and assay with in-house claims, and the limits are as per specifications of APi manufacturer. Column Condition: API manufacturer – Agilent Zorbax SB-C18 (240mm x 4.6mm x 5 micron or equivalent); FPP manufacturer – ODS (150mm x 4.6mm x 5 micron)
The peaks at approx. 1.19, 1.31, 1.50 and 3.73 (RT) are present in the chromatogram of initial assay, but not in that of standard. Justify/clarify.	The extra small peaks in chromatogram of assay sample is due to presence of excipients which are used in the formulation whereas no extra small peak in chromatogram of standard as the standard contains only pure active ingredient.
The innovator product has time of 15 minutes for dissolution test as per pharmacology and biopharmaceutics review. You have set it 30 minutes. Justify.	We have formulated our applied product "Aglizon Tablets (Dapagliflozin)" as film coated tablets & as per USP , disintegration time for film coated tablet is NMT 30 minutes for in-vitro test. We have performed In-vitro test not in–vivo.
Tailing factors and theoretical plates are missing in the chromatogram of API and finished product (assay, dissolution and stability data).	The firm did not submit the same.

In comparative dissolution profile, justify the use 06 tablets instead of 12 tablets, and the peaks in the chromatograms of samples, which are not present in those of standard.	Please note that the comparative dissolution profile (CDP) of newly applied molecules was carried out in the past by using 06 units. However, we assure you to conduct CDP by using 12 units each of reference and sample product in future & for the same we are in-process to purchase 12 to 14 units dissolution apparatus.
You have not performed drug-excipients compatibility study by submitting that stated composition of developed product is similar to innovator's product formulation. However, you have added talc powder in your formulation, which is not used in the innovator's product. Justify/clarify.	Please note that the Innovator used Talc as excipient in coating process & in our formulation, Talc is used as a Lubricant agent to improve the flow property in granulation stage. This is an inert material which do not have any therapeutic effect & is the part of formulation either used in granulation or coating process. We are enclosing herewith the reference page from Handbook of Pharmaceutical Excipients for Role of Talc for your ready reference in Annex – X.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC: Firm has submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.

Decision: Registration Board decided to approve registration of "Aglizon 5mg Tablet (Dapagliflozin 5mg) and Aglizon 10mg Tablet (Dapagliflozin 10mg) by M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2201.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 90mg Each film-coated tablet contains: Etoricoxib…90mg (Innovator's specifications)	Form-5 Dy. No: 15706 Dated 07.03.2018 Rs.20,000/- As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA			
Drug	Etory Tablet 90mg		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura		
Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
9.	COA of API	Yes
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:		
Administrative Portion		
20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information. Batch No.: ACE 01319 Mfg Date: January, 2018 ➢ **Details of ADC attested commercial Invoice** Invoice No. KPLEXP/156/18-19 Quantity imported: 25 Kg Date of import: 22.01.2019 ADC Attestation Date: 30.01.2019 Manufacturer: NOT MENTIONED Batch No.: ACE 01319
22.	Documents for the procurement of reference standard and impurity standards.	No. but CoA of working standard, impurity I and impurity II are attached
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.
24.	Mechanism for Vendor pre-qualification	➢ The firm has submitted Vendor evaluation Form. Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.
25.	Certificate of analysis of the API, reference standards and impurity standards	• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.
26.	Documents for the procurement of excipients used in product development?	Yes
27.	List of qualified staff involved in product development with relevant experience.	The firm has submitted list of three qualified staff involved in product development.
Production Data		
28.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of following documents for development of FPP: **g.** Development protocol. **h.** Stability Study Protocol.
29.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/790</td></tr>
<tr><td>ETR-PB-010001</td><td>02-2019</td><td>1000/806</td></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/984</td></tr>
</table>
</td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>790</td><td>430</td></tr>
<tr><td>ETR-PB-010001</td><td>1000</td><td>806</td><td>440</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>984</td><td>430</td></tr>
</table>
</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td>The firm has referred to analytical method of the API manufacturer.</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Only method for dissolution and HPLC assay.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30°C±2 °C, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>36.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is qualitatively similar to innovator’s product formulation.</td></tr>
<tr><td>37.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
<tr><td>Brand name</td><td>Etoricoxib Tablet 90mg</td></tr>
<tr><td>Batch No.</td><td>1805005040</td></tr>
<tr><td>Exp. date</td><td>02.2020</td></tr>
</table>
</td></tr>
<tr><td>38.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Yes</td></tr>
<tr><td colspan="3">Remarks of Evaluator:
<table>
<tr><th>Shortcomings communicated</th><th>Response by the firm</th></tr>
<tr><td>The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.</td><td>In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8
As per PAR 85% are results, not limits.</td></tr>
</table>
</td></tr>
</table>

	Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.
The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.
As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.

You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.
The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2202.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 120mg Each film-coated tablet contains: Etoricoxib…..120mg (Innovator's specifications)	Form-5 Dy. No 15707 dated 07-03-2019 Rs20,000/- Dated 06-03-2019As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA	
Drug	Etory Tablet 120mg
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura

Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
9.	COA of API	Yes
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

<table>
<tr><td>20.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection report of their product “Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg”, which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board.
Following observations were reported in the report:
✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA
✓ The firm has audit trail Reports on testing.
✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.</td></tr>
<tr><td>21.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information.
Batch No.: ACE 01319
Mfg Date: January, 2018
➢ <u>Details of ADC attested commercial Invoice</u>
Invoice No. KPLEXP/156/18-19
Quantity imported: 25 Kg
Date of import: 22.01.2019
ADC Attestation Date: 30.01.2019
Manufacturer: NOT MENTIONED
Batch No.: ACE 01319</td></tr>
<tr><td>22.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No. but CoA of working standard, impurity I and impurity II are attached</td></tr>
<tr><td>23.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.</td></tr>
<tr><td>24.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.</td></tr>
<tr><td>25.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.</td></tr>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted list of three qualified staff involved in product development.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
d. Development protocol.
e. Stability Study Protocol.</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/790</td></tr>
<tr><td>ETR-PB-010001</td><td>02-2019</td><td>1000/806</td></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/984</td></tr>
</table></td></tr>
</table>

30.	Record of remaining quantities of stability batches.	<table><tr><th>Batch</th><th>Size (tablets)</th><th>Yield (tablets)</th><th>Remaining (tablets)</th></tr><tr><td>ETR-PB-010002</td><td>1000</td><td>790</td><td>430</td></tr><tr><td>ETR-PB-010001</td><td>1000</td><td>806</td><td>440</td></tr><tr><td>ETR-PB-010002</td><td>1000</td><td>984</td><td>430</td></tr></table>
QA / QC DATA		
31.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Yes
32.	Method used for analysis of API along with COA.	No, only method for HPLC assay.
33.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	• Only method for dissolution and HPLC assay. • Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
34.	Reports of stability studies of API from manufacturer.	The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30ºC±2 ºC, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.
35.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.
36.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is qualitatively similar to innovator's product formulation.
37.	Record of comparative dissolution data.	pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. **Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.** <table><tr><th>Feature</th><th>Reference product</th></tr><tr><td>Brand name</td><td>Arcoxia tablet 120mg</td></tr><tr><td>Batch No.</td><td>1805005040</td></tr><tr><td>Exp. date</td><td>02.2020</td></tr></table>
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes

Remarks of Evaluator:

Shortcomings communicated	Response by the firm
The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.	In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8 As per PAR 85% are results, not limits. Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug

	release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.
The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.
As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.
You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.

The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Response by Firm: Firm has submitted stability studies at both accelerated and long term conditions with revised specifications of Dissolution i.e., "NLT 85% within 15 minutes" at initial and one month time point. Details are as follows:

Etory 90 mg tablet:

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	96.26%
			ETR-TB-010002	95.57%	97.96%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	99.27%
			ETR-TB-010002	95.57%	98.81%

Etory 120mg tablet

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.82%
			ETR-TB-011002	100.16%	99.43%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.06%
			ETR-TB-011002	100.16%	100.55%

Decision: Registration Board decided to approve registration of "Etory Tablet 90mg (Etoricoxib) and Etory Tablet 120mg (Etoricoxib) by M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2203.	M/s. Macter International Limited, F-216, S.I.T.E, Karachi.	Vireof-N 25mg Tablets. Each film coated tablet contains: Tenofovir alafenamide (as fumarate)… 25mg	Duplicate dossier	Approved in US-FDA The firm was granted GMP certificate based on inspection conducted on 14-03-2017.

STABILITY STUDY DATA

Drug	Vireof-N 25mg Tablets.		
Name of Manufacturer	M/s. Macter International Limited, F-216, S.I.T.E, Karachi		
Manufacturer of API	Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai.		
API Lot No.	DBH251-B15A-180802		
Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1, 3,6 (month) Real Time: 0,1, 3,6 (month)		
Batch No.	001P	002P	003P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	Sep- 2018	Sep- 2018	Sep- 2018
No. of Batches	03		
Date of Submission	15-04-19 (Dy. No. 3603)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
9.	COA of API	Applicant has submitted the following: **Copy of COA** **From**:Shengai Desano Chemical Pharmaceuticals**Batch No**: DBH251-B15A-180802

10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: Copy of GMP Certificate: **Certificate No:** SH2017046 **Issued To**: Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai. **Issued ON**: 04-12-2017 **Valid Till**: 3-12-2022 **Issued By**: China Food & Drug Administration.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Applicant has submitted Coy of Commercial invoice attested by ADC on 27-08-18 having following information on it: **Invoice Number**: DL-Y-2018-0208 **Manufacturer of API**: Desano Limited. No. 1479, Zhangheng Road, Zhangliang Hi- Tech Park, Shanghai 201203, China. Tenofovir Alafenamide Fumarate API: 1kg Tenofovir Alafenamide Fumarate API W/S: 4g Impurity 1: 100mg Fumaric acid: 100mg Impurity 2: 100mg
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Vireof-N Tablet 25mg (TenofovirAlafenamide Fumarate) Tablets by M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 14th Nov, 2019.
Investigation Date and Time: 18th December, 2019.
Investigation Site: M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Macter International Ltd., F-216, S.I.T.E, Karachi for registration of Vireof-N Tablet 25mg (Tenofovir Alafenamide Fumarate) Tablets. PE&R Division considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and also advised to verify:

"Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM".

Composition of Panel:

4. Prof. Dr. Ghulam Sarwar, ex-member Registration Board, Dean faculty of Pharmacy, Jinnah University for Women, Karachi.

5. Dr. Affan Ali Qureshi, Assistant Director (CDL) DRAP, Karachi.
6. Dr. Kirshan Das, Assistant Director DRAP Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

S. No.	Question	Observation
38.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate API including approval from DRAP?	The firm has imported 1Kg Tenofovir Alafenamide Fumarate (API) from Shanghai Desano Chemical Pharmaceutical Co., Ltd.)vide invoice No. DL-Y-2018-0208 dated: 27.08. 2018. There is proper approval from DRAP Karachi Form 6 (2440-17).
39.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer of API is the vendor evaluation process based on audit and other criteria like manufacturer GMP status, DMF source etc.
40.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate reference standard and impurity standards?	The firm has imported Tenofovir Alafenamide Fumarate working standard and two impurities standards from the API manufacturer.
41.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has Certificate of Analysis of API, working standard of API and impurities standards.
42.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificates for API manufacturer issued by China Food & Drugs Administration valid till 03/12/2022.
43.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method of testing.
44.	Do you have stability studies reports on APIs?	The firm has stability studies report on API (Tenofovir Alafenamide Fumarate) conducted by API manufacturer.
45.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of API has performed the stability studies as per SIM method. The process related impurities and degradation product ie. Impurity I have been observed.
46.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying impurities.
47.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API (Tenofovir Alafenamide Fumarate) working standard and impurity standard.
48.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Microcrystalline cellulose, Lactose Monohydrate ,Croscarmellose sodium, Magnesium stearate

49.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
50.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records for the excipients used.
51.	Do you have written and authorized protocols for the development of Tenofovir Alafenamide Fumarate Tablets?	The firm has written and authorized protocol for the development Tenofovir Alafenamide Fumarate Vireof-N tablets 25mg.
52.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug Excipient compatibility studies as composition of their product is similar to that of innovator product (VEMLIDY tablets 25mgfrom GILEAD Ontario Canada.
53.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of their product with VEMLIDY 25mg batch # CBNKMD of GILEAD and found comparable to the innovator product.
54.	Do you have product development (R&D) section	The firm has product development (R&D) section with requisite manufacturing, storage and analysis facilities.
55.	Do you have necessary equipments available in product development section for development Tenofovir Alafenamide Fumarate Tablets?	The firm has all the necessary equipment available in product development section for the development of Tenofovir Alafenamide Fumarate tablets now, however, the product in question was manufactured in routine production area.
56.	Are the equipment in product development section qualified?	The equipments in product development section and production area are qualified.
57.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.
58.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff in PD section with proper knowledge and training in Product Development including 04 Pharmacists 05 MSc Chemistry and 01 M.Phil.
59.	Have you manufactured three stability batches for the stability studies of Tenofovir Alafenamide Fumarate Tablets required?	The firm has manufactured three stability batches as follows; **Tenofovir Alafenamide Fumarate 25mg tablets:** **Sr. No. / B. No. / Batch size** 1 / 001P / 5000 2 / 002P / 5000 3 / 003P / 5000 The tablets are packed in Alu Alu blisters with pack size 3 x 10's.
60.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tablets required per testing frequency and number of testing frequencies.
61.	Do you have complete record of production of stability batches?	The firm has complete records of production of stability batches. All log books are properly maintained.
62.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for the stability testing of Tenofovir Alafenamide Fumarate tablets.
63.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated method for testing of stability batches of finish product i.e. Tenofovir

		Alafenamide Fumarate tablets based on the API method of testing provided by the API manufacturer.
64.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The firm has developed and validated method based on API manufacturer for testing of finished product, so method transfer studies were required.
65.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir Alafenamide Fumarate and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API (Tenofovir Alafenamide Fumarate) and the finished drug Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg.
66.	Do your method of analysis stability indicating?	The firm's method of analysis is stability indicating as evidence by forced degradation studies and spiking studies of the two major impurities.
67.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR compliant as per record available with the firm.
68.	Can you show Audit trail reports on Tenofovir Alafenamide Fumarate testing?	Audit Trail on the testing reports on Tenofovir Alafenamide Fumarate API and Vireof-N tablets 25mg is available.
69.	Do you have some remaining quantities of degradation products and stability batches?	The firm has only remaining quantities of stability batches kept on real-time stability testing.
70.	Do you have stability batches kept on stability testing?	The firm has three lab scale batches kept on stability studies for real time stability testing. Currently 12 months studies have been completed with satisfactory results.
71.	Do you have valid calibration status for the equipment used in Tenofovir Alafenamide Fumarate Tablets production and analysis?	The firm has valid calibration status for the equipment used in Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg production and analysis.
72.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system for stability chambers.
73.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipments, personnel and utilities are GMP compliant.
74.	Any other query raised by PE&R Division: Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM.	As per firm they have adopted Dissolution method as recommended by US-FDA. The medium is 50 mM Sodium Acetate buffer pH 4.5, Apparatus is USP type II, RPM is 75 which are same as recommended by USFDA. The sampling time is 30 mins which is the maximum time point mentioned on the website of USFDA under dissolution data, however the NDA document of VEMLIDY shows the sampling time to be 15 mins. The firm states that F2 was calculated in CDP at 10 mins because the drug was dissolved more than 90% within 5 mins which shows the formulation complies with innovator as well as US-FDA recommendation. The firm has also performed dissolution testing on an additional time point of 15 month of stability studies and observed the result at 15 minutes and found more than 90% release, which complies with innovator and US-FDA recommendations.

Conclusions:

8. On the basis of risk based approach the genuineness / authenticity of stability data including dissolution method submitted by the firm for registration of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg is verifiable satisfactory level.
9. The related manufacturing area, equipments, personnel and utilities are GMP compliant and well suited for the manufacturing of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg.
10. The case is submitted before Registration Board for decision please.

Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Sr. No.	Deferred for :	Submitted following:
2.	Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.	Applicant has submitted stability studies data for following three batches at following time points: **Batches:** Batch No: P004, P005, P006 **Testing Frequency:** Initial: 1 month: real time plus accelerated. Sampling Time: 15 minutes Drug release at 15 minute sampling interval: Above 90% for all trials at Ist month, as per data submitted by the firm. However data submitted by the firm is in dates before the meeting was carried out & decision of the case was made.

Decision of 295th meeting: Deferred for clarification since the dissolution testing at 15 minutes time point for 2 batches was carried out before the date of conduction of 293rd meeting of Registration Board.

Firm's response: We would like to clarify that the new batches 004P, 005P & 006P were manufactured on 20th December, 2019 immediately after the Product specific Panel inspection held on 17th, December, 2019 on behalf of detailed discussion with panel members. We are also enclosing copy of Form-06 & consumption report of API (for your ready reference). Also it is our usual practice to perform product development activities before launching of the product. We hope that the above justification will be sufficient to clarify the situation.

Decision: Registration Board decided to approve registration of "Vireof-N 25mg Tablets (Tenofovir alafenamide (as fumarate)) by M/s. Macter International Limited, F-216, S.I.T.E, Karachi. Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

f. Verification of stability study data

2204	**Name and address of manufacturer / Applicant**	**"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"**
	Brand Name +Dosage Form + Strength	Boschofen 400mg Infusion
	Composition	"Each 100ml Vial Contains: Ibuprofen……400mg"
	Diary No. Date of R& I & fee	Dy. No 12247 dated 03-04-2018 Rs.20,000/- Dated 28-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia

	Me-too status (with strength and dosage form)	Inbufin infusion of M/s Searle IV solutions (Reg.#094023)
	GMP status	GMP inspection dated 03-12-2018 concluding acceptable level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA			
Drug	Boschofen 400mg Infusion		
Name of Manufacturer	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"		
Manufacturer of API	Ibuprofen: M/s Pharmagen Ltd., Lahore, Pakistan.		
API Lot No.	00510211/001/2018		
Description of Pack (Container closure system)	Transparent glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	TR-BFI-02	TR-BFI-03	TR-BFI-04
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		
Date of Submission	06-05-2019 (Dy. No. 5265)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate for M/s Pharmagen Ltd. Lahore, issued on the basis of inspection conducted on 08-01-2019
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	--
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Boschofen 400mg/100ml (Ibuprofen) Infusion by M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 26th, December, 2019.
Investigation Date and Time: 8th July, 2020 (Afternoon).
Investigation Site: Factory premises of M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Background:
Chairman Registration Board considered the applications of M/s Bosch Pharmaceutical, Bosch House 221, Sector 23, Korangi Industrial Area, Karachi for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

10. Dr. Rafeeq Alam Khan, Meritorious Professor, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
11. Dr. Sanam Kausar Jahan, Assistant Director, CDL, DRAP, Karachi.
12. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

S. No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Firm has procured 0.4kg Ibuprofen from M/S Pharmagen ,Lahore
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which includes GMP Status, provision of DMF, reference standard, impurity standards etc.
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	The firm has obtained API reference standard from API manufacturer.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs and working standards
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided GMP certificate issued by Drug Regulatory Authority of Pakistan.
Q.No.6	Do you use API manufacturer method of testing for testing API?	The firm has used the manufacturer method of testing of API to carryout analysis.
Q.No.7	Do you have stability studies reports on API?	The firm has stability studies reports from API manufacturer conducted on 03 batches for accelerated and real time condition.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability data of API provided by manufacturer is stability indicating and degradation products has been quantified.
Q.No.9	Do you have method for quantifying the impurities in the API?	The firm has used the analysis method provided by the manufacturer of API for quantification of impurities in API.

Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had arranged 0.4kg of Ibuprofen API out of which 0.07 kg was still available in firm .Remaining quantities of working standard and impurity standards were also available.
Q.No.11	Have you used pharmaceutical grade excipients?	The firm used pharmaceutical grade excipients.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm has proper documents for import of the used excipients.
Q.No.13	Do you have test reports and other records on the excipients used?	The firm has Analytical reports for all excipients used in product development of Boschofen infusion.
Q.No.14	Do you have written and authorized protocols for the development of applied product?	The firm had written and authorized protocol for development of Boschofen infusion .
Q.No.15	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator's product and also stability studies have not shown any incompatibility or significant degradation.
Q.No.16	Have you performed comparative dissolution studies?	Not Applicable.
Q.No.17	Do you have product development (R&D) section	The firm has dedicated area for product development.
Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	The firm has necessary equipment for manufacturing of stability batches.
Q.No.19	Are the equipments in product development section qualified?	All equipment in product development section is qualified.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance /calibration plan for equipment in product development section and maintenance /calibration are carried out accordingly.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff in product development section with relevant work experience.
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	Firm has manufactured three stability batches for the stability studies of Boschofen infusion. Batch No : TR-BFI-02 Batch No : TR-BFI-03 Batch No : TR-BFI-04
Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of vials per testing and the number of vials required for whole stability testing.
Q.No.24	Do you have complete record of production of stability batches?	The firm has complete record for manufacturing of three batches of Boschofen Infusion.
Q.No.25	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of stability batches.

Q.No.26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated the method for the testing of Boschofen infusion.
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has complete record of qualification of equipment's /instruments used for test and analysis of API and Boschofen infusion .
Q.No.29	Is your method of analysis stability indicating?	The method of analysis for finished product is stability indicating .
Q.No.30	Is your HPLC software is 21CFR compliant? (Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.))	The HPLC used for analysis of stability batches is Water e2650 with auto sampler and gradient system and it was 21CFR compliant as per record available with firm.
Q.No.31	Can you show Audit Trail reports on stability studies testing?	The firm has demonstrated the audit trail reports for the data submitted for Boschofen infusion.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	The firm had some remaining quantities of stability batches.
Q.No.33	Do you have stability batches kept on stability testing?	The firm has completed accelerated studies whereas, samples are kept for real time stability studies.
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	The firm has valid calibration status for all the equipment /instruments used in production and analysis of the Boschofen infusion .
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	The firm has two separate Stability chambers for Real time and accelerated studies which are equipped with data loggers.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area ,Equipment ,personnel and utilities can be rated as cGMP compliant

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Boshofen 400mg/100ml Infusion.

Decision: Registration Board decided to approve registration of "Boschofen 400mg Infusion (Ibuprofen) by M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

2205.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5738: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/850 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s,14’s, 20’s, 28’s, & 30’s
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/850mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/850mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted comparative dissolution profile of applied product against the reference product, instead firm has submitted CDP data for the higher strength i.e., Xiga-met 5/1000 against the reference product Xigduo.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India		
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	XMA-T5-19	XMA-T6-19	XMA-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

2206.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5739: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/1000 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s,14’s, 20’s, 28’s, & 30’s
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/1000mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/1000mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution profile of applied product against the reference product, Xigduo (batch# X1888A) in three buffers i.e., pH 1.2, pH 4.5 & pH 6.8 with acceptable value of f2 factor.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India		
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	XMB-T5-19	XMB-T6-19	XMB-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Xiga-Met 5/1000 Tablet & Xiga-Met 5/850 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.

Date of Inspection	2nd – 3rd July, 2020
Purpose of Inspection	Verification of authenticity of stability data for purpose of registration of drugs with reference DRAP's letter no. F.1-2/2020-PEC dated 22-04-2020.
Name of Inspector	01. Dr. Muzammal Waheed Director, DTL, Faisalabad. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Hafiz Ahsan Assistant Director, DRAP, Islamabad.

Q. No.	Contents	Remarks
37	Do you have documents confirming the import of Dapagliflozin Propanediol Monohydrate and Metformin HCl including approval from DRAP?	**Dapagliflozin Propanediol Monohydrate:** The firm has imported Dapagliflozin Propanediol Monohydrate raw material vide invoice no. HN190124-C dated 24-01-2019 from M/s. Fuxin Long Rui Pharmaceutical Co., Ltd., China and got DRAP approval vide no. 1757/2019/DRAP dated 01-02-2019. **Metformin Hydrochloride:** The firm has imported Metformin HCl raw material vide invoice no.

		92002215 dated 10-12-2018 from M/s. Wanbury Ltd., India and got DRAP approval vide no. 16536/2018/DRAP dated 19-12-2018.
38	What was the rationale behind selecting the particular manufacturer of API?	The firm selected API manufacturers based on their vendor evaluation mechanism.
39	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Dapagliflozin Propanediol Monohydrate working standard from API supplier dated 27-06-2019. The firm imported Metformin HCl working standard and impurity standard (Metformin HCl Compound A) from API supplier dated 28-05-2019.
40	Do you have certificate of Analysis of the API, reference standards and impurity standards?	**Dapagliflozin Propanediol Monohydrate:** The firm has certificates of analysis for API and working standard. **Metformin HCl:** The firm has certificates of analysis for API, working standard and impurity standard.
41	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	**Dapagliflozin Propanediol Monohydrate**: The firm has valid GMP Certificate of M/s. Fuxin Long Rui, China issued by Fuxin Food & Drugs Administration, China valid till 27-09-2020. **Metformin HCl:** The firm has valid GMP Certificate of M/s. Wanbury Ltd., India issued by Directorate of Drugs Control Administration, Andhra Pradesh valid till 06-02-2022.
42	Do you use API manufacturer method of testing for testing APIs?	The firm has used API manufacturer's method of testing. *Moreover, the firm was advised to develop method transfer protocol for testing APIs.*
43	Do you have stability studies reports on APIs?	The firm had stability studies reports of APIs from API manufacturer: **Dapagliflozin Propanediol Monohydrate**: Accelerated (40ºC±2ºC/RH75%±5%) –6 months Real time (30ºC±2ºC/RH65%±5%) – 24 months **Metformin HCl:** Accelerated (40ºC±2ºC/RH75%±5%)– 6 months Real time (30ºC±2ºC/RH75%±5%) – 60 months
44	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer had performed stability as per SIM method and Metformin HCl Compound A impurity had been quantified.
45	Do you have method for quantifying the impurities in the API?	The firm had testing method to quantify Metformin HCl Compound A impurity as provided by API manufacturer.
46	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Nil.
47	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Avicel pH 102, Klucel EXF, Polyvinylpyrolidone, Aerosil 200, Magnesium stearate, Opadry AMB purple (88A200006) and Opadry white (85G28725).

48	Do you have documents confirming the import of the used excipients?	The firm had necessary documents confirming the import of the used excipients.
49	Do you have test reports and other records on the excipients used?	The firm had certificates of analysis of the excipients used.
50	Do you have written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?	The firm had written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.
51	Have you performed Drug-excipient compatibility studies?	The firm had performed drug-excipient compatibility studies under stress conditions of 60°C ± 2°C / RH 75% ± 5%.
52	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Xiga-Met 5/1000 Tablet with Xigduo 5/1000 Tablet, manufactured by M/s. AstraZeneca, USA using paddle apparatus at 100rpm in 900ml of the following dissolution mediums: 4. HCl buffer 5. Acetate buffer 6. Phosphate buffer
53	Do you have product development (R&D) section	The firm had product development (R&D) section.
54	Do you have necessary equipment available in product development section for development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?	Product development section has necessary equipment to develop Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.
55	Are the equipment in product development section qualified?	The available equipment in product development section were qualified *however, the firm was advised to perform qualifications of equipment from authorized bodies.*
56	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.
57	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes.
58	Have you manufactured three stability batches for the stability studies of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet as required?	The firm has manufactured three initial stability batches for the stability studies of Xiga-Met 5/850 Tablet with batch numbers i.e. XMA-T5-19, XMA-T6-19 and XMA-T7-19 and of Xiga-Met 5/1000 Tablet with batch numbers i.e. XMB-T5-19, XMB-T6-19 and XMB-T7-19. The accelerated studies were done in Climatic test chamber (Model: HPP-749; Making Memmert, Germany) and long-term studies were done in Climatic test chamber (Model: HPP-750, Making Memmert, Germany).
59	Do you have any criteria for fixing the batch size of stability batches?	The firm had followed in-house SOP for fixing the batch size of stability batches.

<table>
<tr><td>60</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of stability batches:
<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td colspan="3">Xiga-Met 5/850 Tablets</td></tr><tr><td>XMA-T5-19</td><td>2,000</td><td>03-2019</td></tr><tr><td>XMA-T6-19</td><td>2,000</td><td>03-2019</td></tr><tr><td>XMA-T7-19</td><td>2,000</td><td>03-2019</td></tr><tr><td colspan="3">Xiga-Met 5/1000 Tablets</td></tr><tr><td>XMB-T5-19</td><td>2,000</td><td>03-2019</td></tr><tr><td>XMB-T6-19</td><td>2,000</td><td>03-2019</td></tr><tr><td>XMB-T7-19</td><td>2,000</td><td>03-2019</td></tr></table></td></tr>
<tr><td>61</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm had protocols for testing of stability batches.</td></tr>
<tr><td>62</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had developed method of Xiga-Met 5/850 Tablet (RD-PTM-16 C) and Xiga-Met 5/1000 Tablet (RD-PTM-17 C) and validated the test method (CCL-AMVR-220) for testing of stability batches.</td></tr>
<tr><td>63</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable.</td></tr>
<tr><td>64</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Dapagliflozin Propanediol Monohydrate and Metformin HCl API and the finished drug?</td><td>The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished product. However, the firm was advised to qualify the equipments / instruments from authorized bodies.</td></tr>
<tr><td>65</td><td>Do your method of analysis stability indicating?</td><td>The firm had conducted stress testing of finished product.</td></tr>
<tr><td>66</td><td>Do your HPLC software 21CFR Compliant?</td><td>API testing, FPP testing and compatibility testing had been conducted on HPLCs which were not 21 CFR compliant.
However, the firm has procured 21 CFR part 11 compliant HPLC.</td></tr>
<tr><td>67</td><td>Can you show Audit trail reports on Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 testing?</td><td>Initially, audit trail was not enabled. However, log of data was available on the HPLCs. The data was also checked through hard copies of chromatograms.
However, 6 months onwards stability studies were performed on audit trail active software.</td></tr>
</table>

<table>
<tr><td>68</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches kept on stability testing:
<table><tr><th>Batch No.</th><th>Batch Size</th><th>Tablets used for stability studies</th><th>Remaining Quantities of Stability Btaches</th></tr><tr><td colspan="4">Xiga-Met 5/850 Tablets</td></tr><tr><td>XMA-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr><tr><td>XMA-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr><tr><td>XMA-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr><tr><td colspan="4">Xiga-Met 5/1000 Tablets</td></tr><tr><td>XMB-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr><tr><td>XMB-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr><tr><td>XMB-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr></table></td></tr>
<tr><td>69</td><td>Do you have stability batches kept on stability testing?</td><td>The firm had stability batches kept on stability testing.</td></tr>
<tr><td>70</td><td>Do you have valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablets production and analysis?</td><td>The firm had valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 production and analysis.</td></tr>
<tr><td>71</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Adequate monitoring and control was available for stability chamber. The firm was advised to improve alarm system.</td></tr>
<tr><td>72</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>Requisite facilities are satisfactory and GMP compliant (DRAP ref. no. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 valid for 3 years).</td></tr>
</table>

VERIFICATION:

(ii) The firm selected M/s. Fuxin Long Rui Pharmaceutical Co. Ltd., China for Dapagliflozin Propanediol Monohydrate based on their vendor evaluation mechanism. Panel verified following documents regarding source:

- ADC attested invoice
- Trial cards

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. CCL Pharmaceuticals (Pvt.) Ltd., at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan have conducted stability studies of the following products. However few points are being recorded for the kind perusal of the Drug Registration Board, against questions 6, 19, 28, 30, 31 and 35 of the check list.

Decision: Registration Board decided to approve registration of "Xiga-Met 5/850 Tablet & Xiga-Met 5/1000 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

d. Exemption from onsite verification of stability data

2207.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.**
	Brand Name +Dosage Form + Strength	**Lina 5mg tablets**
	Composition	Each film coated tablet contains: Linagliptin ……5mg
	Diary No. Date of R& I & fee	Dy. No 1271 dated 28-11-2016, Rs.50,000/- 24-11-2016
	Pharmacological Group	Anti-diabetes
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Lina 5mg tablets		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.		
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China		
API Lot No.	161031		
Description of Pack (Container closure system)	Alu/Alu blister in unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,1,2,3,4,5,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	LNA-PB-005002	LNA-PB-005003	LNA-PB-005004
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	December 2017	December 2017	December 2017
Date of Initiation	December 2017	December 2017	December 2017
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	• Copy of COA for Linagliptin (Batch# 161031) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.
Protocols followed for conduction of stability study and details of tests.	Yes

Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
161031	HK1701121-B	80gm	20-03-2017

All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Lina tablets 5mg and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 09-05-2019 (R&I no. 5661)

Administrative Portion

20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: iv. The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA v. The firm has audit trail Reports on testing. vi. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
161031	HK1701121-B	80gm	20-03-2017

22.	Documents for the procurement of reference standard and impurity standards.	No document has been submitted to establish the procurement of reference standard and impurity standards.
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.
24.	Mechanism for Vendor pre-qualification	• The firm has submitted document of "Rationale for Selection of manufacturer of API 'Linagliptin'"

<table>
<tr><td>25.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>The firm has submitted certificate of analysis for API, working standard & impurity standards.</td></tr>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in Research & product development & scientific Development and Analytical services comprising of 19 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted authorized photocopy of Product Development Protocol & Stability protocols for applied product.</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Lina 5mg tablet such as.
<table>
<tr><th colspan="3">Lina 5 mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>LNA-PB-005002</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005003</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005004</td><td>12-2017</td><td>2000 Tablets</td></tr>
</table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning details of the remaining quantities of tablets kept at accelerated and real time stability studies.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical charts for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Linagliptin.</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Specification/Testing Method of Finished Product for Lina 5mg tablets along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc. for applied formulation.</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Linagliptin</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Lina 5mg tablet.</td></tr>
<tr><td>36.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has stated that they have similar qualitative formulation as that of the innovator product.</td></tr>
<tr><td>37.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted results for comparative dissolution results in 0.1N HCl buffer against the reference product “Tradjenta tablets 5mg”.
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Jenner</th></tr>
<tr><td>Brand name</td><td>Tradjenta tablets 5mg</td><td>Lina 5mg tablet</td></tr>
<tr><td>Batch No.</td><td>655575</td><td>LNA-PB-005002</td></tr>
</table></td></tr>
</table>

		• Firm has submitted f2 factor value for each time point.
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Firm has submitted method audit trail reports of stability studies of applied formulations.

Remarks of Evaluator:

Sr. #	Observations	Response of Firm
1	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) as written in finished product specifications	The analysis is performed for sample solutions and standard solutions in dissolution is 0.005mg/ml as already mentioned in whole stability studies testing records. In finished product specifications, by typing mistake, 2ml is written instead of 1 ml which lead to read as 0.01mg/ml instead of 0.005mg/ml. (It is just typing mistake and is rectified)
2	Retention time of 1st Month stability studies is about 5 mints whereas on all other time points is about 3 mints	Retention time at whole stability studies is about 3 mints instead of 1st Month time point analysis, which is about 5 minutes. **Remarks:** The pressure of HPLC column was increased at 1st Month analysis time point due to which retention time for both sample and standard solution was increased to about 5 minutes from 3 minutes. After that we rectified it and separate column is specified for whole stability studies of said product. Further, more analytical method validation is performed and retention time during AMV was also about 3 minutes.
3	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) in dissolution at 1st month time point analysis	As earlier discussed in point 3, In finished product specifications, by typing mistake, 2ml is written instead of 1 ml. The problem was rectified and analysis at all time points were performed at 0.005mg/ml concentration after this time point.

Decision of 296th meeting: Registration Board decided to approve registration of "Lina 5mg tablets (Linagliptin)" by M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration letters shall be issued after decision on comments of IPO regarding patent matter for the applied formulation.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2208	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43103 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA
STABILITY STUDY DATA				
Drug		Jarzin-Met 5/850mg Tablets		

Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/19030439		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	May 2019	May 2019	May 2019
Date of Initiation	May 2019	May 2019	May 2019
Batch Nos.	**19PD-109**	**19PD-119**	**19PD-120**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2209	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/500mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43106 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA			
Drug	Jarzin-Met 12.5/500mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/18102071		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Feb 2019	Mar 2019	Mar 2019
Date of Initiation	Mar 2019	Mar 2019	Mar 2019
Batch Nos.	**19PD-039**	**19PD-065**	**19PD-067**
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare

			Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.	
Protocols followed for conduction of stability study and details of tests.			Yes	
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.			Yes	
Documents confirming import of API etc.			**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg	
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.			Yes	
Commitment to continue real time stability study till assigned shelf life of the product.			Yes	
Commitment to follow Drug Specification Rules, 1978.			Yes	
Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2210	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/1000mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 1000mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43104 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by USFDA
STABILITY STUDY DATA				
Drug		Jarzin-Met 12.5/1000mg Tablets		
Name of Manufacturer		M/s The Searle Company Limited.		
Manufacturer of API		**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.		**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19010053		
Description of Pack (Container closure system)		Alu-Alu Blister in unit carton		
Stability Storage Condition		**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency		**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date		03 2019	04 2019	04 2019
Date of Initiation		04 2019	05 2019	05 2019

Batch Nos.	**19PD-087**	**19PD-100**	**19PD-102**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2211	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43105 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA

Drug	Jarzin-Met 12.5/850mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.

Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19030439		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	04 2019	04 2019	May 2019
Date of Initiation	May 2019	May 2019	May 2019
Batch Nos.	**19PD-105**	**19PD-106**	**19PD-108**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.		
15.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
17.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
18.	Stability study data of API from API manufacturer	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
21.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
22.	Method used for analysis of FPP	Submitted
23.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
24.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.

25.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]:		

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**	**Evaluated by**
2212	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/500mg Tablets Each film-coated tablet contains: Empagliflozin …… 5mg Metformin HCl …… 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43095 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS	AD PEC-II

STABILITY STUDY DATA

Drug	Jarzin-Met 5/500mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.
Manufacturer of API	**Empagliflozin**: M/s Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl:** M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin HCl**: MEF/17091410
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months

Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Apr 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-086**	**18PD-099**	**18PD-090**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Previous Remarks of Evaluator:

- Salt from of Metformin is not mentioned in Form 5-D.
- Firm has submitted that "the material Empagliflozin" having batch no. D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.
- Content uniformity test has not been performed for Empagliflozin to determine uniformity of dosage unit.
- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability

2213	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/1000mg Tablets Each film-coated tablet contains: Empagliflozin…….5mg Metformin HCl …….1000mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43102 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS

STABILITY STUDY DATA			
Drug	Jarzin-Met 5/1000mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin**: MEF/17091410		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Mar 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-084**	**18PD-087**	**18PD-098**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	

Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator:

- Salt form of Metformin is not mentioned in Form 5-D.
- The acceptance criteria of dissolution test submitted by firm for applied formulation is NLT 75% (Q) after 30 minutes for both Metformin HCl & Empagliflozin. While the dissolution specification of the innovator product i.e., "Synjardy", revealed in Clinical Pharmacology & Biophartmaceutics review by USFDA (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206111Orig1s000ClinPharmR.pdf) declares the dissolution specification for 20 minutes for all strengths of both drug substances i.e., Metformin HCl & Empagliflozin.
- Firm has submitted that "the material Empagliflozin" having batch no D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.
- Upon communication of above observation the firm has referred to following definition of "re-test period", from Annex 2 (Stability testing of active pharmaceutical ingredients and finished pharmaceutical products) of WHO Technical Report Series, No. 953, 2009:

re-test period

"The period of time during which the API is expected to remain within its specification and, therefore, can be used in the manufacture of a given FPP, provided that the API has been stored under the defined conditions. After this period a batch of API destined for use in the manufacture of an FPP should be re-tested for compliance with the specification and then used immediately. **A batch of API can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification.** For most substances known to be labile, it is more appropriate to establish a shelf-life than a re-test period. The same may be true for certain antibiotics."

- Moreover, firm has submitted that they have not performed "Residual solvents testing" & "Chiral impurity testing" at the time of re-test since both these are process related impurities and if they are within specification than there is no need to further analyze at stability & at re-test.

- It is pertinent to mention that as per applicable guidelines, the API could be used immediately (within one month) after the retest, but one time retest analysis could not be used to extend the shelf life of the API in term of retest date.

- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Decision of 293rd meeting: Registration Board deferred the cases for following reasons:

- Clarification/Justification shall be submitted by the firm for extending shelf life of the API for 1 year on the basis of one-time retest.
- Stability studies of Empagliflozin API from the API manufacturer.
- Submission of revised Form 5 with correct composition, declaring the salt form of Metformin.

Firm's response:

- Firm has referred to their SOP of "Retesting of Raw materials".

- For Empagliflozin firm has submitted both accelerated stability studies (6 months) & long-term stability studies report (36 months) of three batches from the API manufacturer.
- Revised Form 5 D with correct composition, declaring the salt form of Metformin as "Metformin HCl" has been submitted.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION		
Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet and provided the following documents in conjunction with the checklist approved by the Registration Board.		
15.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
17.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
18.	Stability study data of API from API manufacturer	**Metformin HCl:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches. **Empagliflozin:** Firm has submitted both stability studies & long term stability studies reports of three batches
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
21.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
22.	Method used for analysis of FPP	Submitted
23.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
24.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet

25.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies for 5/1000mg tablet in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator^{II}:		
Decision: Registration Board decided to approve registration of "Jarzin-Met 5/1000mg Tablets, Jarzin-Met 5/500mg Tablets, Jarzin-Met 12.5/850mg Tablets, Jarzin-Met 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets and Jarzin-Met 5/850mg Tablets by M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan. Manufacturer will place first three commercial batches of all 6 products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

2214.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 800mg Tablets
	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..800mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator^{II}	

2215.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 200mg Tablets
	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..200mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Esli Tablet	
Name of Manufacturer	"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."	
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India	
API Lot No.	Eslicarbazepine acetate: 17EA00012	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Esli 200mg tablet	Esli 800mg tablet
Batch#	ESL-289310-3, ESL-289210-2, ESL-289010-1	ESL-290311-7, ESL-290211-6, ESL-290111-5
Batch Size	1554 Tablets	421 Tablets
Manufacturing Date	Oct-2018	Nov-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Provided
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate # 19061470) issued to M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data	Yes

Batch No.	**Invoice No.**	**Quantity Imported.**
17EA00012	EL/2021700092	2Kg

/ documents.	
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Esli 200mg & 800mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: iv. The HPLC software is 21 CFR compliant. v. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. vi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted. **Batch No.** | **Invoice No.** | **Quantity Imported.** 17EA00012 | EL/2021700092 | 2Kg
22.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted a non-commercial invoice from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India for the import of 1000mg of working standard
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• The firm has provided copy of GMP ceretificate (Certificate # 19061470) issued to M/s M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Hubeii Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.
24.	Mechanism for Vendor pre-qualification	• The firm has submitted photocopy of "SOP for Selection of manufacturer for API/Excipient and Procurement Procedure", SOP No: PDV-FM-068 with effective date 02-03-2018. Version no: 01 • Copy of "Vendor's Audit form" filled for M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India
25.	Certificate of analysis of the API, reference standards and impurity standards	• The firm has submitted certificate of analysis for API (Batch# 17EA00012), working standard (Batch#WS/EA/03) for Eslicarbazepine acetate.

<table>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 17 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted photocopy of Development Protocol `for Lab scale batch manufacturing of Esli 200mg & 800mg Film coated tablets.<br>• Project code # HPL/10/18/ESL<br>• Issued on Oct, 2018<br>• The SOP mentions` the details of master formulation & manufacturing method for both products. Copies of stability protocols have also been submitted for both products.</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Vonopran tablets, such as.

<table>
<tr><th colspan="3">Esli 200mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>ESL-289010-1</td><td>Oct-2018</td><td>1554 Tablets</td></tr>
<tr><td>ESL-289210-2</td><td>Oct-2018</td><td>1554 Tablets</td></tr>
<tr><td>ESL-289310-3</td><td>Oct-2018</td><td>1554 Tablets</td></tr>
<tr><th colspan="3">Esli 800mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>ESL-290111-5</td><td>Nov-2018</td><td>421 Tablets</td></tr>
<tr><td>ESL-290211-6</td><td>Nov-2018</td><td>421 Tablets</td></tr>
<tr><td>ESL-290311-7</td><td>Nov-2018</td><td>421 Tablets</td></tr>
</table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet for all trial batches of both Esli 200mg & 800mg tablets.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Eslicarbazepine acetate
• Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs have been submitted.</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for Esli 200mg tablets & Esli 800mg tablet along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Eslicarbazepine acetate from API manufacturer for both Accelerated (40˚C ± 2˚C / 75% ± 5%RH) 6 months & Long term (30˚C ± 2˚C / 65% ± 5%RH) conditions for 48 months only.</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Esli tablets.</td></tr>
<tr><td>36.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet and</td></tr>
</table>

<table>
<tr><td></td><td></td><td>also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>37.</td><td>Record of comparative dissolution data.</td><td>
• Firm has submitted F2 factor protocol & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Esli 200mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 200mg tablet</td><td>Esli 200mg tablet</td></tr>
<tr><td>Batch No.</td><td>ZBCB</td><td>ESL-289210-2</td></tr>
<tr><th colspan="3">Esli 800mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 800mg tablet</td><td>Esli 800mg tablet</td></tr>
<tr><td>Batch No.</td><td>PXFZ</td><td>ESL-290111-5</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
d. pH 1.2 HCl buffer
e. pH 4.5 Acetate buffer
f. pH 6.8 Phosphate buffer
• As per submitted reports both reference and trial product are comparable as with acceptable f2 value.
• Firm has submitted UV spectrums and raw data sheets for the CDP study.
</td></tr>
<tr><td>38.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td colspan="3">Remarks of Evaluator^{II}:</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Esli 800mg Tablets (Eslicarbazepine Acetate) and Esli 200mg Tablets (Eslicarbazepine Acetate) M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.</td></tr>
</table>

2216.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 90mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…….90mg"
	Diary No. Date of R& I & fee	Dy. No 1243 dated 10-01-2019, Rs.20,000/- Dated 10-01-2019
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer’s specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance
	Remarks of the Evaluator[II]	

2217.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 60mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor……60mg"
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013, Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Tri-Plat Tablets 60mg	
Name of Manufacturer	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"	
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1, SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India.	
API Lot No.	8281034.	
Description of Pack (Container closure system)	Alu-Alu blister in unit carton	
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Trip-Lat 60mg	Trip-Lat 90mg
Batch#	Trial#01, Trial#02, Trial#03	Trial#01, Trial#02, Trial#03
Batch Size	1500 Tablets	1500 Tablets
Manufacturing Date	05-2019	06-2019

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Trip-Lat 60mg & 90mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.

15.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Saferon tablets (Sofosbuvir 400 mg)", which was presented in 278th meeting of Registration Board held on 29-31st Jan, 2018 **Observations:** Panel has observed that firm has improved as follows: • Floor has been renovated and painted with epoxy paint (anti-bacterial). • Old windows were replaced with double glazed windows.

<table>
<tr><td></td><td></td><td>• Special Aluminium fixtures with rounded edges were installed.
• Upgraded HVAC with pressure differentials was provided.
• Firm has 06 tablet compression machines with capability of producing double layered tablets.
Keeping in view improvements made by the firm as identified in the previous inspection, panel recommends the facilities of the firm for manufacturing of Saferon (Sofosbuvir 400mg) tablets and give rating of very Good.
Decision: Registration Board decided to approve registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
<tr><td>16.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Submitted</td></tr>
<tr><td>17.</td><td>Method used for analysis of API along with COA.</td><td>Firm has submitted COA and method of analysis of API.</td></tr>
<tr><td>18.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.</td></tr>
<tr><td>19.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate (No. 19011176) for M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1,SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India issued by Food & Drug Control Administration, Gujarat State, valid upto 08-08-2021.</td></tr>
<tr><td>20.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Firm has submitted following.
•Commercial invoice attested by AD (I&E) DRAP, Islamabad dated 22-10-2018, Islamabad confirming import of Ticagrelor (1.125Kg), Batch# 8281034.</td></tr>
<tr><td>21.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Firm has submitted authorized protocols for the development of Trip-Lat Tablets.</td></tr>
<tr><td>22.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>23.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.</td></tr>
<tr><td>24.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the three batches.
<table>
<tr><th colspan="3">Tri-Plat 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><th colspan="3">Tri-Plat 90mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>06-2019</td><td>1500 Tablets</td></tr>
</table></td></tr>
</table>

25.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Brilinta tablet for both strengths concluding f2 value within acceptable limit.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Trip-Lat 60mg & 90mg tablets
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]: • Submitted batch manufacturing record declare use of 3% overage of API.		
Decision: Registration Board decided to approve registration of "Tri-Plat Tablets 60mg (Ticagrelor) and Tri-Plat Tablets 90mg (Ticagrelor) by M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IV-A conditions.		

Case no. 07 Applications on Form 5F

2218.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28339: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…60mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA

	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China		
API Lot No.	RD-TG- 201810081		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.

8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision:

2.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28340: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s, 14’s, 20’s, 28’s & 30’s
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018

	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China		
API Lot No.	RD-TG- 201810081		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.

9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Observation	**Firm's response**
Justify the dissolution specification NLT 80%(Q) after 45 minutes, since the USFDA chemistry review document of the innovator product specify dissolution testing at two points i.e. NLT (Q) at 45 minutes and NLT (Q) at 60 minutes. • USFDA guidelines "dissolution testing of Immediate release solid oral dosage form" recommends that for slowly dissolving or poorly water soluble drugs, a two point dissolution specification, one at earlier time to include a dissolution range (a dissolution window) and the other at a later point (30, 45 or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product. The innovator product has also used the same approach and selected two time points for dissolution, justify how your finished product specification without a test for measure of dissolution range at 45 minutes & at 60 minutes to ensure 85% drug release be considered similar to that if innovator product. If your product shows more than 85% release in 45 minutes, how it can be considered similar with innovator product in terms of drug release	• As per USFDA guidelines *"dissolution testing of Immediate release solid oral dosage form"* Two time point dissolution analysis is recommended for development studies of BCS class II drugs and after development the final dissolution specifications will be set while the Ticagrelor falls in BCS class IV and many pharmacopeal monograph of BCS class IV and II available in pharmacopeia having only one time interval for dissolution test i.e. Clarithromycin , Leflunomide - • Furthermore, According to FDA chemistry review, the agency recommend the applicant (Innovator) to submit a supplement to set the final acceptance criteria for dissolution testing. • It is also mentioned in FDA reviews of Innovator data that the product shows consistent results at 45 minutes and the agency recommend to revised the proposed dissolution • To ensure the release pattern of SAMI product same as Innovator product, Comparative dissolution against innovator at different time point (i-e 45 and 60 minutes) has been performed and both products achieve the dissolution more than 80%(Q) after 45 minutes.**)** • We have also done testing at both time intervals i.e. 45 & 60 minutes at 9th month stability study at long term on stability batches • On the basis of above we have set the specification for dissolution i-e NLT 80% (Q) at 45 minutes.

Decision: Registration Board deferred the applications of Taglor 60mg Tablet & Taglor 90mg tablet and directed the firm to submit dissolution testing data with time pints of 45 minutes & 60 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

2219.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"**

	Name, address of Manufacturing site.	"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2207: 21-02-2020
	Details of fee submitted	PKR 20,000/-: 18-02-2020
	The proposed proprietary name / brand name	**D-3 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each ml Contains: Cholecalciferol…….5mg"
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Vitamin D (A11CC05)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1ml x 1's, 1ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by ANSM of France
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharmaceuticals (Reg.#063450)
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 28-11-2019.
	Name and address of API manufacturer.	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Product:	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Pharmaceutical Equivalence	Firm has submitted comparison analysis studies against the reference product of Bouchara Recordati France.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data for the assay test performed by UV spectrophotometer.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
API Lot No.	CLC0419019
Description of Pack (Container closure system)	1 ml clear glass ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml
Batch Size	10000 Ampoules	10000 Ampoules	10000 Ampoules
Manufacturing Date	06-2019	06-2019	06-2019

Sr.#	Data required	Status
7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Canzin tablets", which was conducted on 14-03-2019, and was presented in 289th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail on testing reports is available.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (No. 181529) issued by the Jiangsu Drug Administration in the name of M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India has been submitted which was valid upto 02-01-2020.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. RV1002100166) attested by AD DRAP Karachi dated 09-04-2019, for import of 0.2Kg of Cholecalciferol (batch# CLC0419019)
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

- Firm has used 15% overage in the master formulation and submitted following justification for it:
  "Vitamin D3 is a heat sensitive material, when used as an active ingredient, cannot be terminally sterilized therefore subjected to filtration through microbial retentive materials. It is aseptically filled and sterilized by filtration by using 0.2um filter which have high chances of clogging and absorption. The assay limit is therefore set at 95% - 105% at the time of release, as API is lost during filtration process. Hence, 15% overage is used to compensate the process loss."
  Whereas, our result in accelerated stability are within the limit which justify the assay limit of 90% - 110% for shelf life. However, we undertake that we will revise our limit with 90% to 115% in finished product specification."
- Firm has applied UV method for the Assay analysis of drug product during stability studies.

Decision: Deferred for justification of performing Assay analysis of the drug product by UV spectrophotometric method.

2220.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"**
	Name, address of Manufacturing site.	"M/s Hiranis Pharmaceuticals (Pvt.) Ltd.

		Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No28011: 23-12-2019
	Details of fee submitted	PKR 50,000/-: 23-12-2019
	The proposed proprietary name / brand name	**Etoxib tablet 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each film coated tablet contains: Etoricoxib …… 30mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	COX-2 inhibitor
	Reference to Finished product specifications	Manufacturer specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	Rs. 200/tablet
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	M/S Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India.
API Lot No.	84170527
Description of Pack	Alu-Alu blister in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	TF-051118	TF-061118	TF-071118
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	11-2018	11-2018	11-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by the FDA Maharashtra India in the name of M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India has been submitted which is valid upto 24-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
84170527	F2000002386	100Kg	01-03-2018

REMARKS OF EVALUATOR[II]:

Observation	Firm's response
Justification of 5% overage in the formulation(s) of stability batches shall be submitted since Overages are not acceptable unless fully justified.	This addition was not due to any specific reason, however we have reviewed the stability data of these three trial batches and noted that Assay & Dissolution results remain well within limits without significant change after 6 months accelerated stability. Furthermore we have evaluated that 5% overage impact on assay & Dissolution results and if we subtract 5% overage

	impact on assay & dissolution values, our values are still within limits. Furthermore we hereby commit that in commercial batch formulation of Etoxib tablet 30mg, overage will not be included.

Decision: Registration Board decided to approve registration of "Etoxib tablet 30mg (Etoricoxib) by M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

2221.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals, S-95, SITE, Karachi.**
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23129: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 2.5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 2.5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20180205Y		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
2222.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23128: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s, 20’s, 30’s
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Remarks of Evaluator: • Stability studies of drug substance as per Zone IVa conditions have been submitted.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.

	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 5mg tablet and the results are within acceptable limit of f2 value.			
STABILITY STUDY DATA				
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China			
API Lot No.	20180205Y			
Description of Pack (Container closure system)	Alu-Alu blister in unit carton			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	Lab-01	Lab-02	Lab-03	
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.	
Manufacturing Date	12-2018	12-2018	12-2018	
Date of Initiation	01-2019	01-2019	01-2019	
No. of Batches	03			
REQUEST OF EXEMPTION FROM ON SITE INSPECTION				
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.				
7.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.		
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.		
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).		
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
12.	Record of Digital data logger for temperature and humidity	Submitted		

	monitoring of stability chambers (real time and accelerated)	
Decision: Registration Board decided to approve registration of "Xaby 2.5mg tablet (Apixaban) and Xaby 5mg tablet (Apixaban) by M/s Sami Pharmaceuticals, S-95, SITE, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

Item No. -: Agenda of Evaluator PEC-VIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

b. New cases

2451.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …120mg"
	Diary No. Date of R& I & fee	Dy.No 9382 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	----
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator VIII	Applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2452.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …60mg"
	Diary No. Date of R& I & fee	Dy.No 9380 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Starcox 60 mg tab by Getz Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator VIII	
	Decision: Approved as per innovator's specification.	

2453.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox 500mg Tablets
	Composition	"Each dispersible contains: Deferasirox…500mg"
	Diary No. Date of R& I & fee	Dy.No 9378 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 500mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved as per innovator's specification.	
2454.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox250mg Tablets
	Composition	"Each dispersible contains: Deferasirox…250mg"
	Diary No. Date of R& I & fee	Dy.No 9379 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2455.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 100mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…100mg"
	Diary No. Date of R& I & fee	Dy.No 9374 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA

	Me-too status	Tics 100mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2456.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 200mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…200mg"
	Diary No. Date of R& I & fee	Dy.No 9375 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 200mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2457.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 1000mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…1000mg"
	Diary No. Date of R& I & fee	Dy.No 9362 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicia 1000mg Tablet of Martin Dow
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2458.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 750mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…750mg"
	Diary No. Date of R& I & fee	Dy.No 9361 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Vetrawin Tablets 750mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2459.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 500mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…500mg"
	Diary No. Date of R& I & fee	Dy.No 9360 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Vetrawin Tablets 500mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2460.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Danon Tablets 4mg
	Composition	"Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…4mg"
	Diary No. Date of R& I & fee	Dy.No 9376 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zofran tablet 4mg of Glaxo welcome
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2461.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Serna Tablets 100mg

	Composition	"Each Film Coated Tablet Contains: Sertraline (as hydrochloride)…100mg"
	Diary No. Date of R& I & fee	Dy.No 9370 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	SSRIs
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Saytral 100mg Tablets of Sayyed Pharmaceuticals
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2462.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Grezon 90mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Diary No. Date of R& I & fee	Dy.No 9986 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2463.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 145mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…145mcg"
	Diary No. Date of R& I & fee	Dy.No 9978 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2464.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 72mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…72mcg"
	Diary No. Date of R& I & fee	Dy.No 9977 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2465.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 290mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…290mcg"
	Diary No. Date of R& I & fee	Dy.No 9979 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2466.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Luzon 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lurasidone (ashydrochloride)…40mg"
	Diary No. Date of R& I & fee	Dy.No 9980 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(uncoated)Latuda (ema film)
	Me-too status	-----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Reference Product is approved as uncoated tablet which is different from applied formulation submit either composition & master formulation after correction alongwith submission of requisite fee or evidence of reference product approved as film coated tablet.
	Decision: Deferred for the following: • **Submit either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **Submit either composition & master formulation after correction along with submission of requisite fee as reference product is approved as uncoated tablet or otherwise evidence of reference product approved as film coated tablet.**	
2467.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 12.5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9972 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019

	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (JARDIAMET 12.5 mg/850 mg)
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2468.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9973 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA JARDIAMET 5 mg/850 mg
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2469.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Linazin Tablet 25/5mg
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No. 9969 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	7's,14's,28's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Glyxambi25 mg/5 mg tablets)
	Me-too status	----

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.
	Decision: Deferred for the following: • **Submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **For opinion of Legal Affairs Division regarding linagliptin for its patent rights.**	
2470.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Bimzin Eye Dop 0.3mg/ml
	Composition	"Each ml contains: Bimatoprost…0.3mg"
	Diary No. Date of R& I & fee	Dy.No 9966 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-glaucoma
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	15ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (solution) (LUMIGAN: 0.03% **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Lumigan eye Drops of Barret Hodgson
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2471.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Detozin Injection 2ml
	Composition	"Each 2ml ampoule contains: Dexketoprofentrometamol 73.80mgeq to Dexketoprofen…50mg"
	Diary No. Date of R& I & fee	Dy.No 9967 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	5's,10's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were

		declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.
	Decision: deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
2472.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	TimprostOpthalmic Solution 50mcg/5mg
	Composition	"Each ml contains: Latanoprost…50mcg Timolol(as maleate)…5mg"
	Diary No. Date of R& I & fee	Dy.No 9976 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Prostaglandin analogue, antiglaucoma drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	2.5ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (solution)
	Me-too status	Latlol eye drops of Genix
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2473.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Dilatic Tablet 500mcg
	Composition	"Each Film Coated Tablet Contains: Roflumilast…500mcg"
	Diary No. Date of R& I & fee	Dy.No 10673 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Phosphodiesterase-4 (PDE-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30,s:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2474.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nepawal 1mg/1ml Opthalmic Solution
	Composition	"Each ml of opthalmic suspension contains: Nepafenac…1mg"
	Diary No. Date of R& I & fee	Dy.No 10672 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	3ml, 5ml(LDPE bottle):As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(suspension)
	Me-too status	Venac 0.1% of Vega Pharma
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2475.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Artazon3ml Injection
	Composition	"Each ml contains: Atracurium besilate…10mg"
	Diary No. Date of R& I & fee	Dy.No 10615 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Nondepolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's,10's :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicurium injection 10mg/ml of Elite Pharma (2.5ml)
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	*MHRA 2.5 ml: Type I glass ampoule in packs of 5 ampoules. 5 ml: Type I glass ampoule in packs of 5 ampoules. 25 ml: Type I glass vial with rubber stopper in packs of 1 vial. • Evidence of approval of applied formulation in applied volume i.e. 3ml in reference agencies. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Submit Me Too in applied volume.

	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting in applied volume i.e 3ml.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in applied volume i.e 3ml..**	
2476.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nevazon 5/80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…5mg Valsartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 10674 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	beta blocker/ angiotensin receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	-----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2477.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 50mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…50mg"
	Diary No. Date of R& I & fee	Dy.No 9373 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 50mg Tablet of Genix Pharma
	GMP status	Dated: 26-04-2019 GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator VIII	
	Decision: Approved.	
2478.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Nitaxid 100mg/5ml Dry Suspension
	Composition	"Each 5ml Suspension after Reconstitution Contains:

		Nitazoxanide…100mg"
	Diary No. Date of R&I & fee	Dy.No 40911 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	30ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Nitox 100mg /5ml of M/s Regal Pharmaceuticals,
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 13. General Tablet Section 14. General Capsule Section 15. Oral Dry Powder Suspension Section(General) 16. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2479.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Diclowin 50mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg" (core, enteric coating)
	Diary No. Date of R&I & fee	Dy.No 40927 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Dicmaf 50mg Tablet of Mafins
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 17. General Tablet Section 18. General Capsule Section 19. Oral Dry Powder Suspension Section(General) 20. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2480.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Serat 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline as hydrochloride…50mg"

	Diary No. Date of R&I & fee	Dy.No 40932 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Saytral 50mg Tablets of Sayyed Pharmaceuticals
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 21. General Tablet Section 22. General Capsule Section 23. Oral Dry Powder Suspension Section(General) 24. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2481.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Eprijen 50mg Tablet
	Composition	"Each sugar coated tablet contains: Eperisone HCL…50mg"
	Diary No. Date of R& I & fee	Dy.No 39902 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in PMDA
	Me-too status	Feloni 50mg Tablet of Hirani Pharmaceutical,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2482.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Rolajen 500mg XR Tablets
	Composition	"Each extended release tablet contains: Ranolazine …500mg"
	Diary No. Date of R& I & fee	Dy.No 40848 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	cardiac preparations
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)TGA
	Me-too status	Ranagin XR 500mg of Hilton Pharma

	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit manufacturing method for relevant formulation as submitted method is of film coated tablet.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product.	
2483.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	"Jenfine Tablets 125mg
	Composition	"Each Tablet Contains: Terbinafine(as HCL)…125mg
	Diary No. Date of R& I & fee	Dy.No 39905 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Antifunga
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA& TGA
	Me-too status	Logirid Tablet 125mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision:Approved.	
2484.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Setrom 8mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ondansetron dihydrate eq to Ondansetron …8mg"
	Diary No. Date of R& I & fee	Dy.No 40296 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Zofran Tablets 8mg of Glaxo Wellcome Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
2485.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Histajen 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ebastine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40843 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE

	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Desid Tablets 10mg ofGillman Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
2486.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jen-Heim Tablet
	Composition	"Each chewable tablet contains: Iron III Hydroxide polymaltose complex eq to elemental iron…100mg Folic Acid…0.35mg"
	Diary No. Date of R& I & fee	Dy.No 40852 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	RBC-F tablets by Genix
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2487.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenprox SR Tablets 12.5mg
	Composition	"Each SR Tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 39906 dated 04-12-2018 Rs.20,000/
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Panox CR Tablet 12.5 mg of M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant & in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable

		barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 12.5 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2488.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jentadin Tablets 5mg
	Composition	"Each Film Coated Tablet Contains: Desloratadine…5mg"
	Diary No. Date of R& I & fee	Dy.No 39907 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	ANTIHISTAMINES
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2489.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Piracet 800mg Tablets
	Composition	"Each Film Coated Tablet Contains: Piracetam…800mg"
	Diary No. Date of R& I & fee	Dy.No 39901 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Troopil Tablets 800 mg of ParamountPharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2490.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Hiace5mg Tablet
	Composition	"Each uncoated tablet contains: Ramipril…5mg"
	Diary No. Date of R& I & fee	Dy.No 41393 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	ACE Inhibitor

	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Ramy 5mg Tablet of Getz Pharma Karachi
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved with USP specifications	
2491.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Diora 50mg Capsule
	Composition	"Each Capsule Contains: Diacerin…50mg"
	Diary No. Date of R& I & fee	Dy.No 41392 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-osteoarthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Dorsett 50mg Capsule of Weather Folds Pharmaceuticals,
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2492.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Renavel 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sevelamer as HCL…400mg"
	Diary No. Date of R& I & fee	Dy.No 41391 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Foseal-800 Tablets Of M/S. Sncura Enterprises

	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	Reference product is "Each Film Coated Tablet Contains: Sevelamer HCL…400mg"
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: "Each Film Coated Tablet Contains: Sevelamer HCL…400mg"	
2493.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Cande 16mg Tablet
	Composition	"Each uncoated tablet contains: Candesartan Cilexetil …16mg"
	Diary No. Date of R& I & fee	Dy.No 41408 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Miscand 16mg Tablet of Mission Pharma.
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	On fee challan strength of tablet is 160 instead of 16.
	Decision: Approved as applied formulation is not available in strength of 160mg.	
2494.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Doxy Tablets 400mg
	Composition	"Each Film Coated Tablet Contains: Doxofylline…400mg"
	Diary No. Date of R& I & fee	Dy.No 40291 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.

	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant.
	Decision: Deferred for submission of manufacturing method for relevant formulation in line with reference product.	
2495.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Ferriject 500mg/10ml Injection
	Composition	Each 10ml Ampoule Contains: Iron as ferric carboxymaltose…500mg
	Diary No. Date of R& I & fee	Dy.No 40162 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (vial)
	Me-too status	Ferinject Injectable.Each 10ml vial contains:- Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2496.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Isofer 1000mg Injection
	Composition	"Each 10 ml Ampoule Contains: Iron as Iron III Isomaltoside…1000mg"
	Diary No. Date of R& I & fee	Dy.No. 40158 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2497.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"

	Brand Name +Dosage Form + Strength	C-Cox 200mg Capsule
	Composition	"Each Capsule Contains: Celecoxib…200mg"
	Diary No. Date of R& I & fee	Dy.No 41057 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Selxib -200mg Capsule OF M/s Fynk Pharmaceuticals,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2498.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Rotcam 20mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Piroxicam…20mg"
	Diary No. Date of R& I & fee	Dy.No 40178 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m route)
	Me-too status	Piroxinor 20mg Injection ofM/s Nortech Pharmaceuticals, Pvt. Ltd
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2499.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden-Plus 75/20 mg Injection
	Composition	Each 2ml Ampoule Contains: Diclofenac Sodium…75mg Lidocaine Hydrochloride…20mg
	Diary No. Date of R& I & fee	Dy.No 40177 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID, Local anesthetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	2ml (10's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Swiss medic Diclofenac Mepha Injection by Mepha Pharm
	Me-too status	Lidoran of Danas Pharma

	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2500.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden 75mg/3ml Injection
	Composition	"Each 3ml Ampoule Contains: Diclofenac Sodium…75mg"
	Diary No. Date of R& I & fee	Dy.No 40222 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m) but status is repealed.
	Me-too status	V-REN Liquid injection of M/s Regal Pharmaceuticals
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2501.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Megatron Plus Syrup
	Composition	Each 5ml Contains: Iron III Hydroxide polymaltose complex…50mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy.No 41132 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Heamatinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	60ml : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

2502.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No 41738 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	14'sAs per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Barclor 250mg Tablet of Brand, Karachi .
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2503.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxflex Tablets 550mg
	Composition	Each film coated Tablet Contains: Naproxen Sodium…550mg
	Diary No. Date of R& I & fee	Dy.No 41727 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Freshnap Tablet 550mg of M/s Fresh Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2504.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxzole Tablets 500/400mg
	Composition	Each Tablet Contains: Diloxanide furoate…500mg Metronidazole…400mg

	Diary No. Date of R& I & fee	Dy.No 41740 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-amoebic infection
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	15's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(as provide by firm) (not verifiable)
	Me-too status	Dizet DS Tablets of M/s Rasco Pharma
	GMP status	Dated: 26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Clarification regarding salt of metronidazole is required.
	Decision: Deferred for clarification regarding salt form of API "Metronidazole" in applied formulation.	
2505.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dicmax Tablets 50mg
	Composition	Each film coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 41728 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Pngo 50mg Tablet of M/s Innvotek Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2506.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 100mg
	Composition	Each Tablet Contains: Atenolol……..…100mg
	Diary No. Date of R& I & fee	Dy.No 41736 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	Me-too status	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2507.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 50mg
	Composition	Each Tablet Contains: Atenolol…50mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta bloker
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Atenocard Tablets 50mg of Fassgen Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation; the firm the advice to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2508.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Famoday Tablet 20mg
	Composition	Each Film coated Tablet Contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Link-Live 20mg Tablet of Umema Pharma
	GMP status	Dated: 26-06-2019 **Conclusion:**

		The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2509.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxtilium Tablets 10mg
	Composition	Each Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 41726 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Epodom 10mg Tablets of Atlantic Pharmaceutical
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2510.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fucimax Cream 2%/1%
	Composition	Each tube contains: Fusidic Acid…2% Hydrocortisone…1%
	Diary No. Date of R& I & fee	Dy.No 41733 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti- inflamatory
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	15gm: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (emc)
	Me-too status	Ucid-HC Cream of Ciba Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit label claim of applied formulation in line with reference. Clarification regarding salt form of Hydrocortisone is required. Evidence of section approval.

	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference.** • **Clarification regarding salt form of Hydrocortisone is required.** • **Evidence of required manufacturing facility i.e., Cream/ ointment section from licensing is required.**	
2511.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxsec Tablets
	Composition	Each Tablet Contains: Amlodipine besylate…5mg
	Diary No. Date of R& I & fee	Dy. No 41737 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Reference product contains Amlodipine as besylate…5mg
	Decision: approved with USP specifications and in line with reference product with following composition: **"Each Tablet Contains:** **Amlodipine as besylate…5mg "**	
2512.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No 41739 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator.	
	Decision:Approved.	
2513.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenmax Tablets 100mg
	Composition	Each film coated Tablet Contains: Diclofenac sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 41730 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed in film coating(enteric coated is available)
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2514.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 5mg Tablet
	Composition	"Each Tablet Contains: Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9094 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as "amlodipine as besylate 5mg tablet", submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition:	

	"Each Tablet Contains: Amlodipine as besylate…5mg "	
2515.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 10mg Tablet
	Composition	"Each Tablet Contains: Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9095 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 10 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as amlodipine as besilate 10mg tablet, submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition: "Each Tablet Contains: Amlodipine as besylate…10mg "	
2516.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9049 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 5/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet. Updated status of GMP from QA & LT Division.	
2517.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 10mg/160mg/25mg

	Composition	Each Film Coated Tablet Contains: Amlodipine …10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9048 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 10/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 10mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet.** **Updated status of GMP from QA & LT Division**	
2518.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 9047 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	As per SRO
	Me-too status	Aldric-H 5/160/12.5mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 12.5mg in a tablet.** **Updated status of GMP from QA & LT Division**	
2519.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/10mg

	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…10mg
	Diary No. Date of R&I & Fee	Dy.No 6334 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…10mg "**	
2520.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 40mg/5mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…40mg Amlodipine besylate…5mg
	Diary No. Date of R&I & Fee	Dy.No 6333 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 40/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…40mg** **Amlodipine as besylate…5mg "**	
2521.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/5mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…5mg

	Diary No. Date of R&I & Fee	Dy.No 6335 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/5mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…5mg "**	
2522.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/5mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9104 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating, submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	

2523.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9103 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2524.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/10mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9105 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation.

		Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.MF contains ingredients of coating.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2525.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/10mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9106 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2526.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"

	Brand Name + Dosage Form + Strength	Amosart 5/40mg Tablets
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9063 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2527.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 10/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 9062 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise

		formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 10mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2528.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 5/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9064 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2529.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 8125 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2530.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 10mg/40mg Tablet
	Composition	Each film coatedTablet Contains: Amlodipine as besylate…10mg Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 8124 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2531.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/80mg Tablet
	Composition	Each film coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 8126 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA

	Me-too status	Telday Plus 5/80 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2532.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8173 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's: Rs.600/-, Rs.840/-, Rs.1200/-, Rs.1680/-, Rs.1800/-, Rs.3600/-, As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2533.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8172 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2534.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8175 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2535.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/10mg
	Composition	Each tablet contains Telmisartan…40mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8174 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2536.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Diary No. Date of R&I & Fee	Dy.No.5953 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist

	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Fenaso 10mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2537.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5952 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Fenaso 5mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2538.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 2mg
	Composition	Each film coated tablet contains: Risperidone…2mg
	Diary No. Date of R&I & Fee	Dy.No 8182 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 2mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2539.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 4mg
	Composition	Each film coated tablet contains: Risperidone…4mg
	Diary No. Date of R&I & Fee	Dy.No 8183 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP Specification

	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 4mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2540.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 10mg
	Composition	Each film coated tablet contains: Rivaroxaban…10mg
	Diary No. Date of R&I & Fee	Dy.No 5957 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Xarelto 10 mg Tabs by Bayer
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2541.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 15mg
	Composition	Each film coated tablet contains: Rivaroxaban…15mg
	Diary No. Date of R&I & Fee	Dy.No 5958 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited,C/21, S.I.T.E.,Karachi."
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2542.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 20mg
	Composition	Each film coated tablet contains: Rivaroxaban…20mg
	Diary No. Date of R&I & Fee	Dy.No 5959 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Rivox Tablet 20 mg of CSH, Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Mention isomeric form of rivaroxaban.(Innovator: S enantiomer)
	Decision: Approved with innovator's specifications.	
2543.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 5mg
	Composition	Each uncoated tablet contains: Aripiprazole…5mg
	Diary No. Date of R&I & Fee	Dy.No 5954 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Ariza 5mg Tablet of Hilton Pharma (Pvt.) Limited Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2544.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 10mg
	Composition	Each uncoated tablet contains: Aripiprazole…10mg
	Diary No. Date of R&I & Fee	Dy.No 5955 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 10mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2545.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 15mg
	Composition	Each uncoated tablet contains: Aripiprazole…15mg
	Diary No. Date of R&I & Fee	Dy.No 5956 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019

	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 15mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2546.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 6.25mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R&I & Fee	Dy.No 6781 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Hidilol 6.25mg Tablets of Helix Pharma (Pvt.) Ltd; Karachi.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2547.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 12.5mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 6782 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 12.5mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2548.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…25mg
	Diary No. Date of R&I & Fee	Dy.No 6783 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019

	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 25mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2549.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Syrup 100mg/5ml(liq)
	Composition	Each 5ml of syrup contains: Doxofylline…100mg
	Diary No. Date of R&I & Fee	Dy.No 5944 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO
	Approval status of product in reference regulatory authorities	Doxofillina ABC 200 mg / 10 ml Syrup by M/s ABC Farmaceutici SpA –Corso Vittorio (Italian Medicine Agency (AIFA) Italy Approved)
	Me-too status	Profylline Syrup 100mg/ 5mlof Kaizen Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2550.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 500mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…500mg
	Diary No. Date of R&I & Fee	Dy.No 5947 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Ursochol 500 mg capsule, hard By Orifarm Generics A/S (Sweden Approved).
	Me-too status	Triptor Capsule 500mg of M/s CCL Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2551.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 250mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 5946 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5

	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Triptor Capsule 250mg of M/s CCL Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2552.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 16mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…16mg
	Diary No. Date of R&I & Fee	Dy.No 5951 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)
	Me-too status	Betoxen 16mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2553.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 8mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…8mg
	Diary No. Date of R&I & Fee	Dy.No 5950 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	3*10's: As per SRo
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)
	Me-too status	Betoxen 8mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2554.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name + Dosage Form + Strength	Barlev Injection 500mg/5ml
	Composition	Each 5ml contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Eplipsa 500mg/5ml Injection of Helix Karachi .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Reference Product:*KEPPRA injection contains 100 mg of levetiracetam per mL. It is supplied in single-use 5 mL vials containing 500mg levetiracetam, water for injection, 45 mg sodium chloride, and buffered at approximately pH 5.5 with glacial acetic acid and 8.2 mg sodium acetate trihydrate. KEPPRA injection must be diluted prior to intravenous infusion. Mention type of primary packaging material.
	Decision: Deferred for submission of type of primary packaging material for applied formulation.	
2555.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Tamlev 100mg/ml oral Solution of Medisure Lab. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is solution you have applied for syrup, clarify.
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2556.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R&I & Fee	Dy.No 9040 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 250mg of M/s Akson Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2557.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"

	Brand Name + Dosage Form + Strength	Ikra 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 9039 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 500mg of M/s Akson Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2558.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 2.5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 5903 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2559.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5904 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	

	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2560.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 10mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…10mg
	Diary No. Date of R&I & Fee	Dy.No 5905 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2561.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 10mg
	Composition	Each Tablet Contains: Bisoprolol…10mg
	Diary No. Date of R&I & Fee	Dy.No 9102 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolol fumarate 10mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 10mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2562.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 2.5mg
	Composition	Each Tablet Contains: Bisoprolol…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 9100 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 2.5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 2.5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2563.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 5mg
	Composition	Each Tablet Contains: Bisoprolol…5mg salt?
	Diary No. Date of R&I & Fee	Dy.No 9101 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2564.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Vorizole Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R&I & Fee	Dy.No 6790 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	JP Specification
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc) (film coated)
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	

	Decision: Approved.	
2565.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mislip Tablet 100mg
	Composition	Each uncoated tablet contains: Amisulpride…100mg
	Diary No. Date of R&I & Fee	Dy.No 6337 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Ampisol 100mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2566.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mislip Tablet 50mg
	Composition	Each uncoated tablet contains: Amisulpride…50mg
	Diary No. Date of R&I & Fee	Dy.No 6336 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Me-too status	Ampisol 50mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2567.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti-arthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	

	Decision: Registration Board decided to approve registration of applied formulation for only hip and knee arthritis.	
2568.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Cancemos 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Capecitabine …500mg"
	Diary No. Date of R&I & Fee	Dy.No 4886 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Pyrimidine analogues
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	120's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Citabin 500mg tablet of m/s. Revive health care
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility.	
2569.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Salmos Syrup 2mg/5ml
	Composition	Each 5ml contains: Salbutamol as sulphate…2mg
	Diary No. Date of R&I & Fee	Dy.No 5323 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Wintol syrup of Lisko
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	*MHRA: 100 ml, 150 ml and 200 ml type III amber glass bottle with Pilfer-Proof cap, screw cap or Child resistant closure. 100 ml and 150 ml HDPE bottle with screw cap, tamper evident cap or child resistant closure
	Decision: Approved as per innovator's specification.	
2570.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg Capsule
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 5325 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	1's, 4's,7's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fiscon capsule 50mg of Fassgen
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2571.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 200mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…200mg"
	Diary No. Date of R&I & Fee	Dy.No 5327 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's, 7's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fcozole 200mg capsule of Medicraft
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2572.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 150mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…150mg"
	Diary No. Date of R&I & Fee	Dy.No 5326 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's, 7's,: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Flu-Z Capsule 150mg of Z-JANS Pharmaceuticals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2573.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg/5ml Suspension (DRY)
	Composition	Each 5ml contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 7274 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	35ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in MHRA(powder for oral suspension)
	Me-too status	Flucal of caliph pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferrred for confirmation of manufacturing facility i.e., "Dry powder suspension" section for applied formulation and revision of label claim.	
2574.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…50mg
	Diary No. Date of R&I & Fee	Dy.No 6784 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 50 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2575.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…100mg
	Diary No. Date of R&I & Fee	Dy.No 6785 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 100 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2576.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Velkeno 2.5mg/5ml Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 5329 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	30ml, 60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Limited (Reg. #054519)
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2577.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R&I & Fee	Dy.No 9050 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2578.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R&I & Fee	Dy.No 9051 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2579.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 100mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…100mg
	Diary No. Date of R&I & Fee	Dy.No 9052 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Lipride tablet 100mg of Polyfine chemicals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2580.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5330 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with reference
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2581.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 40mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5331 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following:	

	Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.	
2582.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R&I & Fee	Dy.No 9065 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 20mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2583.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 9066 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 40mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2584.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 9067 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 80mg of Martin Dow

	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2585.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 40/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9098 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2586.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 80/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9099 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2587.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Mefalgic 50mg/5ml Suspension
	Composition	Each 5ml contains: Mefenamic Acid…50mg

	Diary No. Date of R&I & Fee	Dy.No 5328 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SSRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Constel 50mg/5ml suspension
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	MEntion type of primary packaging material Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Mention type of primary packaging material for applied formulation.**	
2588.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gesic 250mg Tablet
	Composition	Each Tablet Contains: Mefenamic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 7306 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Genston of Genome Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2589.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Secobal 500mcg Tablet
	Composition	Each Film Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R&I & Fee	Dy.No 5324 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's, 100's: as per SRO
	Approval status of product in reference regulatory authorities	PMDA Approved (but sugar coated)
	Me-too status	081876; Brand Name: Heam 500 mcg Tablet Manufacturer Name: Linear Parma,
	GMP status	Dated:04-07-2018

		Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for confirming film coating approval status in reference regulatory authorities.	
2590.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 600mg/2ml
	Composition	Each 2ml contains: Lincomycin as HCL…600mg
	Diary No. Date of R&I & Fee	Dy.No 5939 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	(2ml)::As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lincowrd 600mg Injection of Welwrd Pharmaceutical
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for justification on scientific grounds for not performing terminal sterilization of applied formulation.	
2591.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 300mg/ml
	Composition	Each ml contains: Lincomycin as HCL…300mg
	Diary No. Date of R&I & Fee	Dy.No 5938 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 5's, 10's(1ml): Rs.60/-, Rs.300/-, Rs.600/-, or as per SRO
	Approval status of product in reference regulatory authorities	Approved In USFDA***(could not be not confirmed in applied volume i.e. 1 ml)***
	Me-too status	Farcocine Injection of Farmaceutics Int. Karachi
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Deferred for evidence of approval of applied formulation in applied volume i.e. "1ml" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.**	

2592.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Tablets 400mg
	Composition	Each uncoated tablet contains: Doxofylline…400mg
	Diary No. Date of R&I & Fee	Dy.No 5945 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2593.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 300mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…300mg
	Diary No. Date of R&I & Fee	Dy.No 5949 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	20's, 30's: As per SRO
	Me-too status	
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…300mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2594.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 150mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…150mg
	Diary No. Date of R&I & Fee	Dy.No 5948 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Butrin XL 150mg tablet of Genome
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…150mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2595.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R&I & Fee	Dy.No 5906 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexipin 200mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2596.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R&I & Fee	Dy.No 5907 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexfen 300mg tablet of Hygeia
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2597.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R&I & Fee	Dy.No 5908 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:as per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)

	Me-too status	Dexipin 400mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2598.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Aronic Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Ibandronate Sodium Monohydrateequivalent to ibandronic acid…150mg
	Diary No. Date of R&I & Fee	Dy.No 5943 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	bisphosphonate
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	1's, 3's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Boonset of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2599.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Uro Trate Tablet 10meq
	Composition	Each extended release tablet contains: Potassium citrate…10meq
	Diary No. Date of R&I & Fee	Dy.No 5942 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	urinary alkalinizing agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,20's'30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Urocit-K 10meq Tablets Of Universal Enterprises
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2600.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Onvin Syrup 4mg
	Composition	Each 5ml contains: Ondansetron as Hcl dihydrate…4mg
	Diary No. Date of R&I & Fee	Dy. No 5941 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	50ml, 60ml,120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Not verifiable

	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2601.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Valrate Oral Solution 250mg/5ml
	Composition	Each 5ml of oral syrup contains: Sodium valproate eq to valporic acid…250mg
	Diary No. Date of R&I & Fee	Dy. No 5940 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dipodium of 250mg/5ml syrup of Lexicon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Evidence of approval status of product in reference regulatory authorities is required. Clarification regarding physical form of applied drug product is required (syrup or solution?)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2602.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Baymil Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Bamifylline…600mg
	Diary No. Date of R&I & Fee	Dy.No 6780 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Bamiscot of scottmann
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.	
2603.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO

	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per indications approved by reference regulatory authorities.	
2604.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Barresten HC Cream 10/10mg
	Composition	Each gram contains: Clotrimazole…10mg Hydrocortisone acetate eq to Hydrocortisone…10mg
	Diary No. Date of R&I & Fee	Dy.No 6718 dated 15-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiinfectives And Antiseptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Razole Cream of Ciba Pharmaceuticals, Karachi . .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2605.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Nitazoxanide…500mg
	Diary No. Date of R&I & Fee	Dy.No 6788 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Izato 500mg tablet of Sami
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2606.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Dry Powder Oral suspension 100mg/5ml
	Composition	Each 5ml contains when reconstituted: Nitazoxanide…100mg
	Diary No. Date of R&I & Fee	Dy.No 6789 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification

	Pack size & Demanded Price	30ml, 60ml; As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nitranex 100mg/5ml of Nexus Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2607.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 40mg
	Composition	Each enteric Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…40mg
	Diary No. Date of R&I & Fee	Dy.No 6799 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	7's, 10's, 14's, 20's,28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Nexium tablets
	Me-too status	Zimol 40 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2608.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 40mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate e to Ziprasidone…40mg
	Diary No. Date of R&I & Fee	Dy.No 6796 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Zpras 40mg Capsule of Wellborne Pharmachem
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2609.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zitra Tablet 30mg
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R&I & Fee	Dy.No 6794 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	ANTIDEPRESSANTS
	Type of Form	Form-5
	Finished product Specification	USP Specification

	Pack size & Demanded Price	20's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Zepidep Tablet 30mg of Saydon Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2610.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Torek Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg
	Diary No. Date of R&I & Fee	Dy.No 6793 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2611.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Pirament Syrup 1gm(liq)
	Composition	Each 5ml contains: Piracetam……1gm
	Diary No. Date of R&I & Fee	Dy.No 6786 dated 15-02-2019 Rs.20,000/-
	Pharmacological Group	N06BX: Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Greytone 1000mg/5ml suspension of High-Q
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2612.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…20mg
	Diary No. Date of R&I & Fee	Dy.No 6798 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	7's, 10's,14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved MHRA
	Me-too status	Zimol 20 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2613.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 80mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate eq. to Ziprasidone…80mg
	Diary No. Date of R&I & Fee	Dy.No 6797 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,14's,20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ziprox 80mg Capsule of Nabiqasim Industries
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2614.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 30mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…30mg Source : Vision but stability is not submitted
	Diary No. Date of R&I & Fee	Dy.No 6792 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 30mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2615.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 15mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…15mg Source : Vision but stability is not submitted
	Diary No. Date of R&I & Fee	Dy.No 6791 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019

	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 15mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2616.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Quitapine ST Tablets 300mg
	Composition	Each extended release film coated tablet contains: Quetiapine fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 6795 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Qusel XR 300mg Tablet of Hilton Pharma Karachi . .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Quetiapine as fumarate…300mg extended release tablet.
	Decision: Deferred for submission of lable claim/composition of applied formulation in line with reference product i.e. Quetiapine as fumarate…300mg extended release tablet.	
2617.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Carbofer Injection 500mg/10ml
	Composition	Each 10ml ampoule contains: Iron as ferric carboxymaltose…500mg
	Diary No. Date of R&I & Fee	Dy.No 6977 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA (vial) Ferinject Injectable.Each 10ml vial contains:-
	Me-too status	Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2618.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan

	Brand Name + Dosage Form + Strength	Drospa Fort Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Drotaverine HCL…80mg
	Diary No. Date of R&I & Fee	Dy.No 6961 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	antispasmodic drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA italy
	Me-too status	Relispa Forte Tablets of Searle Pakistan, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2619.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Actirin Capsule 25mg
	Composition	Each Capsule Contains: Acitretin…25MG
	Diary No. Date of R&I & Fee	Dy.No 6964 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	NEOTIGASON CAPSULE 25mg Of MULLER &PHIPPS KARACHI
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2620.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acitirin Capsule 10mg
	Composition	Each Capsule Contains: Acitretin…10MG
	Diary No. Date of R&I & Fee	Dy.No 6963 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	7's, 10's, 14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	ACT 10mg Capsule of Ciba Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	

2621.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 100mg
	Composition	Each uncoated tablet contains: Clozapine…100mg
	Diary No. Date of R&I & Fee	Dy.No 6760 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's,50's, 60's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ekloz 100 mg Tablets of WnsFeild Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2622.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Capsule 40mg
	Composition	Each Capsule Contains: Omeprazole as enteric coated pellets, 8.5%...40mg Source: Vision
	Diary No. Date of R&I & Fee	Dy.No 6956 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2623.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Insta Plus Sachet
	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R&I & Fee	Dy.No 7534 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ruling + Sachet of High-Q,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	

2624.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 500mg/ml
	Composition	Each ml contains: Cefpirome Sulfate …500mg
	Diary No. Date of R&I & Fee	Dy.No 8469 dated 26-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	CEFROM INJECTION 0.5GM of HOECHST MARION ROUSSEL KARACHI
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …0.5gm. Mention type of primary packaging material.
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	
2625.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 1gm/ml
	Composition	Each ml contains: Cefpirome Sulfate …1gm
	Diary No. Date of R&I & Fee	Dy.No 8470 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	ANSM (France) By M/s Saofi Aventis France.
	Me-too status	Cefrom Injection 1gm by M/s Sanofi Aventis (Reg#021124)
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …1gm
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	
2626.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 1.5gm/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…1.5gm
	Diary No. Date of R&I & Fee	Dy.No 8442 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 1.5 g of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 1.5mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	

	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…1.5gm**	
2627.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 750mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…750mg
	Diary No. Date of R&I & Fee	Dy.No 8441 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 750 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 750mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…750mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…750mg**	
2628.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 250mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…250mg
	Diary No. Date of R&I & Fee	Dy.No 8440 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 250 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 250mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…250mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…250mg**	
2629.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox 125mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Cefuroxime Axetil…125mg

	Diary No. Date of R&I & Fee	Dy.No 8467 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Purox 125mg/5ml Dry Suspension of M/s ARP (Pvt) Ltd,
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product is approved as Cefuroxime as axetil…125mg per 5ml suspension.
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each 5ml contains:** **Cefuroxime (as axetil)…125mg**	
2630.	**Deleted: Duplication of Case No.2351**	
2631.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 3mg Tablet
	Composition	Each Tablet Contains: Paliperidone…3mg
	Diary No. Date of R&I & Fee	Dy.No 7276 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2632.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 6mg Tablet
	Composition	Each Tablet Contains: Paliperidone…6mg
	Diary No. Date of R&I & Fee	Dy.No 7277 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.

	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2633.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 1.5mg Tablet
	Composition	Each Tablet Contains: Paliperidone…1.5mg
	Diary No. Date of R&I & Fee	Dy.No 7275 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Palitec XR 1.5mg Tablet of Pharmatec Karachi . .
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2634.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 25mg
	Composition	Each uncoated tablet contains: Clozapine…25mg
	Diary No. Date of R&I & Fee	Dy.No 6959 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Amlepo 25mg Tablet of Amarant
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2635.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Itradex Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole…100mg (IR Pellets) Source: vision
	Diary No. Date of R&I & Fee	Dy.No 8188 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	4's, 8's, 12's: As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2636.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 67mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…67mg
	Diary No. Date of R&I & Fee	Dy.No 8185 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Corfibrate 67mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2637.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Detora Tablet 5mg
	Composition	Each film coated release tablet contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8184 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 100's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lyon 5mg Tablets of Fassgen Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2638.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 4mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…4mg
	Diary No. Date of R&I & Fee	Dy.No 8129 dated 25-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs),
	Type of Form	Form-5
	Finished product Specification	Mfg Specification

	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Canex 4mg Tablets of Wellborne Pharmachem and Biologicals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2639.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Ilop 1mg Tablet
	Composition	Each Tablet Contains: Iloperidone …1mg
	Diary No. Date of R&I & Fee	Dy.No 7278 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	ILOPER 1mg Tablet of Hilton
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2640.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac C 32mg/25mg Tablet
	Composition	Each film coated Tablet Contains: Candesartan…32mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy. No 8130 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Advantec Tablet of Getz Pharma Karachi
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for the following: **Mention salt form of API "Candesartan" in applied formulation along with submission of requisite fee in line with reference product.**	
2641.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 8mg Tablet

	Composition	Each film coatedTablet Contains: Candesartan cilexitil…8mg
	Diary No. Date of R&I & Fee	Dy.No 8127 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 8mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2642.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 16mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…16mg
	Diary No. Date of R&I & Fee	Dy.No 8128 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 16mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2643.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Mednir 250mg/5ml dry powder suspension
	Composition	Each 5ml contains: Cefdinir…250mg
	Diary No. Date of R&I & Fee	Dy.No 8474 dated 26-02-2019 Rs.20,000/- ated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cefnir 250mg/5ml Dry Suspension of Barrett Hodgson Pakistan

	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications.	
2644.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Viptin 50mg Tablet
	Composition	Each Tablet Contains: Vildagliptin…50mg
	Diary No. Date of R&I & Fee	Dy.No 7297 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hypoglycemic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Vilda 50mg of M/s. Rotex Pharma (Pvt) Ltd, Islamabad
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2645.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 200mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…200mg
	Diary No. Date of R&I & Fee	Dy.No 8186 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Corfibrate 200mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2646.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ciricode syrup for oral soultion 100mg
	Composition	Each ml contains: Citicoline as Sodium…100mg
	Diary No. Date of R&I & Fee	Dy.No 6965 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30ml, 60ml,120ml: As per SRO

	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Cercolin Syrup of M/s Schazoo Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2647.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…20mg
	Diary No. Date of R&I & Fee	Dy.No 9058 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10,s: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2648.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…40mg
	Diary No. Date of R&I & Fee	Dy.No 9059 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2649.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 100mg Capsules
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R&I & Fee	Dy.No 9044 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification

	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 100mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2650.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 300mg Capsules
	Composition	Each Capsule Contains: Pregabalin…300mg
	Diary No. Date of R&I & Fee	Dy.No 9046 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 300mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2651.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9075 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiinfectives and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)
	Me-too status	Robecide 200 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee.** **Updated status of GMP from QA & LT Division.**	
2652.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Amlogyl Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…400mg
	Diary No. Date of R&I & Fee	Dy.No 9076 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)
	Me-too status	Robecide 400 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee. **Updated status of GMP from QA & LT Division.**	
2653.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 400mg Tablet
	Composition	Each Tablet Contains: Linezolid…400mg
	Diary No. Date of R&I & Fee	Dy.No 9053 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(zyvox tablet 400mg) (but discontinued, however it is written that Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Barizold tablet 400mg of Barrett Hodgson(Reg #076342)
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2654.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…600mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	LinzolTablet 600 mg of M/s Regal Pharmaceuticals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is film coated tablet
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2655.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 75mg Capsules
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Regab of Caraway pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2656.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Azonax 0.25mg Tablet
	Composition	Each film coated Tablet Contains: Alprazolam…0.25mg
	Diary No. Date of R&I & Fee	Dy.No 9037 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Medilap 0.25mg Tablet of Wellborne Pharmachem and Biologicals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of required manufacturing facility "Tablet psychotropic section" from licensing division.** **Updated status of GMP from QA & LT Division.**	
2657.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 500mg Tablet

	Composition	Each Tablet Contains: Mebendazole…500mg
	Diary No. Date of R&I & Fee	Dy.No 9072 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTINEMATODAL AGENTS
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Leukiban Tablets 100mg of Rakaposhi Pharmaceuticals (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2658.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Viredo B Tablet 300mg
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil as Fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 9061 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	
	Me-too status	
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2659.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 9041 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Levetiracetam Thame 100mg/ml Oral Solution
	Me-too status	Levefil Oral Solution of Pharmatec Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2660.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Amlogyl Suspension 200mg/5ml
	Composition	Each 5ml of suspension contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9074 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Mogel 200mg Suspension of M/s Metro Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2661.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 50mg Capsules
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R&I & Fee	Dy.No 9042 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dygab 25mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2662.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 50mg Tablet
	Composition	Each Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.

	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but outline of method of manufacturing do not contain step of coating.	
2663.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 75mg Tablet
	Composition	Each film coated Tablet Contains: Diclofenac potassium…75mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2664.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lowstat 10mg Tablet
	Composition	Each Tablet Contains: Simvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 7304 dated 20-02-2019 Rs.20,000/-
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(film coated tablet)
	Me-too status	Mistin 10mg Tablet of Mission Pharma.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2665.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hcl…10mg
	Diary No. Date of R&I & Fee	Dy.No 7296 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019

	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2666.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 10mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 9092 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Save-R Tablets 10mg of Wilson's Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…10mg film coated tablet.
	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 10mg in a tablet.** • **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2667.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…20mg
	Diary No. Date of R&I & Fee	Dy.No 9093 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Registration Number 080326 Brand Name

		Restore 20mg Tablet (Rosuvastatin calcium) Manufacturer Name Mission Kar. Manufacturer Address Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…20mg film coated tablet.
	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 20mg in a tablet.** • **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2668.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Moxibax 400mg Tablet
	Composition	Each Tablet Contains: Moxifloxacin Hcl…400mg
	Diary No. Date of R&I & Fee	Dy.No 7309 dated 20-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Avelox 400mg film-coated tablets byM/s Bayerplc,
	Me-too status	Molinza tablet 400mg M/S Zafa
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Moxifloxacin as Hcl…400mg film coated tablet. Master Formulation contains ingredients of coating
	Decision: Deferred for the following: **Submission of Form 5, master formulation, manufacturing method after correction in line with reference product Moxifloxacin as Hcl 400mg film coated tablet.**	
2669.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Atenox Tablet 25mg
	Composition	Each Tablet Contains: Atenolol…25mg
	Diary No. Date of R&I & Fee	Dy.No 9096 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	BETA BLOCKING AGENTS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(uncoated tablet)
	Me-too status	Atomin 25mg Tablet of Semos Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Master Formulation contains ingredients of coating
	Decision: Deferred for the following:	

	Submission of master formulation after correction in line with reference product Moxifloxacin as Hcl…….400mg film coated tablet.	
2670.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Desodine 5mg Tablet
	Composition	Each film coated tablet Contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9089 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet. MF contains ingredients of coating
	Decision: Approved with innovator's specifications.	
2671.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Salazo-En 500mg Tablet
	Composition	Each Tablet Contains: Sulfasalazine…500mg
	Diary No. Date of R&I & Fee	Dy.No 7295 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Zalaz Tablets of Mediate Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as enteric coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Deferred for revision of formulation as per reference product alongiwth requisite fee.	
2672.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart Tablet 80mg
	Composition	Each Film coated tablet Contains: Valsartan…….80mg
	Diary No. Date of R&I & Fee	Dy.No 9091 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in reference regulatory authorities	Valsartan 80mg Film-coated Tablets (MHRA Approved)
	Me-too status	Valseta 80mg Tablet by Maple Pharma (Reg#83347)
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	MF contains ingredients of coating.
	Decision: Approved .	
2673.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 100mg/5ml(dry)
	Composition	Each 5ml contains: Mebendazole…100mg
	Diary No. Date of R&I & Fee	Dy.No 9073 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antinematodal agents
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	30ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc)
	Me-too status	Nemazole Suspension of M/s Nexus Pharma
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Revision of formulation from dry suspension to liquid suspension alongwith submission of requisite fee.** **Updated status of GMP from QA & LT division.**	
2674.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hydrochloride……..…10mg
	Diary No. Date of R&I & Fee	Dy.No 9090 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Registration Board decided to reject the application as same formulation with same brand name is considered in the name of M/s Baxter Pharmaceuticals at serial No. 2387.	
2675.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fyprox CR Tablet 25mg Fyprox CR Tablet 12.5mg
	Composition	Each enteric film coated tablet contains: Paroxetine as Hydrochloride……..…25mg

	Diary No. Date of R&I & Fee	Dy.No 7539 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Deroxat CR tablet 25mg by Global Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Submit composition/label claim of applied formulation in line with product approved in reference agencies i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for submission of composition/label claim and manufacturing method for applied formulation in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 25 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2676.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Oltal F Capsule 3mg/25mg
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine HCL eq to Fluoxetine…25mg
	Diary No. Date of R&I & Fee	Dy.No 7540 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Symbyax 3 mg/25 mg Capsules of Eli Lilly , USA (USFDA)
	Me-too status	Olanzo-F 3/25 mg Capsules of Regal pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2677.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ploro T Injection 40mg/0.04mg
	Composition	Each 4ml ampoule contains: Pholoroglucinol hydrated…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R&I & Fee	Dy.No 7536 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	antispasmodic agent
	Type of Form	Form-5
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	(4ml) 6's: As per SRO
	Approval status of product in reference regulatory authorities	Phloroglucinol/Trimethylphloroglucinol Arrow 40 mg / 0.04 mg per 4 ml, solution for injection by M/s GENERIC ARROW, ANSM France
	Me-too status	Anafortan Plus Injection 40mg/0.04mg (4ml ampoule) by M/s Ali

		Gohar Pharmaceuticals (Pvt) Ltd, Reg. No. 24503
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2678.	**Name and address of manufacturer / Applicant**	**"M/s Walt Danzay Pharmaceuticals. 35-A, Punjab, Small Industrial Estate,Taxila, Paksitan"**
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% Injection
	Composition	Sodium Chloride 0.9% Injection Each ml Ampoule Contains: Sodium Chloride…0.9%w/v"
	Diary No. Date of R& I & fee	Dy.No.21048 dated 12-06-2018 Rs.20,000/-
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's (5ml), (10ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Norsal 0.9% Infusion of Nabiqasim Industries
2679.	GMP status	
	Remarks of Evaluator	• Justification on scientific basis for addition of 3% overage in applied formulation. • Mention quantity of sodium chloride in one ml & submit master formulation accordingly. • Submit separate application for each applied volume. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility & Submit latest GMP inspection report.
	Decision: Registration Board decided to reject the application since DML in the name of M/s Walt Danzy Pharmaceuticals is not valid.	
2680.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Palidol 6mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…6mg"
	Diary No. Date of R& I & fee	Dy.No. 21235 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.

	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2681.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2682.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 5mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No. 21242 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO Rs.182/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nebilol 5mg Tablet of Genix Pharma Karachi
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2683.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**

	Brand Name +Dosage Form + Strength	Tenson10mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21243 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.300/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2684.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 2.5mg Tablet
	Composition	"Each film coated tablet Contains: Nebivolol (as hydrochloride)…2.5mg"
	Diary No. Date of R& I & fee	Dy.No. 21241 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.108/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 2.5mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2685.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Diabet 50mg Tablet
	Composition	"Each Tablet Contains: Vildagliptin…50mg"
	Diary No. Date of R& I & fee	Dy.No. 21239 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018

	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	28's:As per SRO or Rs.1471.08/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Galvus Tablets 50mg Of Novartis Pharma
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2686.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Deferred for submission of evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2687.	**Deleted: Duplication of case at Serial No. 2404**	
2688.	**Deleted: Duplication of case at Serial No. 2405**	
2689.	**Deleted: Duplication of case at Serial No. 2406**	
2690.	**Deleted: Duplication of case at Serial No. 2407**	
2691.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Terbi Aid 250mg Tablet
	Composition	"Each tablet contains: Terbinafine(as hydrochloride)…250mg"
	Diary No. Date of R& I & fee	Dy.No.21655 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA

	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg of M/sNeomedix Pharmaceuticals
	GMP status	
	Remarks of Evaluator	Fee challan is for Terbi Aid 250mg Capsule instead of Terbi Aid 250mg Tablet. Clarification regarding applied formulation is coated or uncoated.
	Decision: Deferred for the following: • **Clarification regarding applied formulation is coated or uncoated.** • **Submit Fee challan for relevant formulation.**	
2692.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group.** **Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Isonic 20mg Capsule
	Composition	"Each hard gelatin capsule contains: Isotretinoin…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21656 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Retinoid for topical use in acne
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	5's, 10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Atractin20mg Capsule of Genome
	GMP status	GMP inspection conducted on 16-03-2017 concluded that firm is operating at good level of GMP compliance.
	Remarks of Evaluator	Evidence of section approval & equipment used in manufacturing of applied formulation is required. Applied formulation is hard shell capsule stability studies may be needed.
	Decision: Deferred for the following: • **Evidence of section approval & equipment used in manufacturing of applied formulation is required.** • **Applied formulation is hard shell capsule so submit stability studies as per guidelines approved in 293rd meeting of Registration Board.**	
2693.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd.** **Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan** **By** **Medisure Lab Pvt Ltd"**
	Brand Name +Dosage Form + Strength	Iroaid 100mg/5ml Injection
	Composition	"Each 5ml contains: Iron sucrose eq. to elemental Iron….100mg"
	Diary No. Date of R& I & fee	Dy.No. 20883 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	

	Me-too status (with strength and dosage form)	Acron S 100mg/5ml Injection of Asian Continental
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.** • **Mention type of primary packaging material of applied formulation.**	
2694.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd.** **Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan** **By** **Medisure Lab Pvt Ltd"**
	Brand Name +Dosage Form + Strength	Seafix 100mg/5ml Suspension
	Composition	"Each 5ml contains: Cefixime (as trihydrate)….100mg"
	Diary No. Date of R& I & fee	Dy.No 20882 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status (with strength and dosage form)	Seaxim Dry Suspension of Semos Pharmaceuticals
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for type of primary packaging material of applied formulation.	
2695.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd.** **E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine(as hydrobromide)…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21069 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.

	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2696.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 97/103 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan…103mg"
	Diary No. Date of R& I & fee	Dy.No.21065 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Neprilysin Inhibitors ,angiotensin receptor blocker,
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2697.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Lacomide 10mg/ml Syrup
	Composition	"Each ml Contains: Lacosamide…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21067 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Anti-epileptic drug
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	60ml,90ml,120ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in Belgium, Germany, Ireland, Malta & UK
	Me-too status (with strength and dosage form)	Lalap syrup 10mg/ml by Genix Pharma (Reg#089376)
	GMP status	Panel Inspection for renewal of DML conducted on 18th & 31st July recommended grant of renewal of DML.
	Remarks Of Evaluator	Applied formulation is new molecule for which submission of stability studies & fee Rupee 50,000 is required.
	Decision: Approved.	
2698.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 49/51 mg Tablet

	Composition	"Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg"
	Diary No. Date of R& I & fee	Dy.No.21066 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks Of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2699.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 24/26 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…24mg Valsartan…26mg"
	Diary No. Date of R& I & fee	Dy.No. 21064 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	------
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2700.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine (as hydrobromide)…10mg"

	Diary No. Date of R& I & fee	Dy.No.21070 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2701.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Palidol 3mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…3mg"
	Diary No. Date of R& I & fee	Dy.No.21234 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2702.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 12.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No. 30866 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953

		Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	
2703.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 25mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 30867 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	

2704.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 37.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 30868 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	

Case no. 02 Registration applications of categories to be considered on priority

b. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

2705.	**Deleted as the case was already approved.**	
2706.	**Deleted as the case was already approved.**	
2707.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oranib 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sorafenib as tosylate…200mg"
	Diary No. Date of R& I & fee	Dy.No 4887 dated 02-02-2019 Rs.20,000/-
	Pharmacological Group	Kinase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications

	Pack size & Demanded Price	10's, 30's, 60's, 120's, :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	NEXAVAR 200MG TABLETS of BAYER PAKISTAN
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing facility.	
2708.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Semotrozole 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Anastrozole…….1mg"
	Diary No. Date of R& I & fee	Dy.No 4885 dated 04-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications
	Pack size & Demanded Price	10's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	ARMOTRAZ TABLETS 1mg Of AJ MIRZA PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2709.	Name and address of manufacturer / Applicant	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha
	Brand Name +Dosage Form + Strength	Lozet 2.5mg Tablet
	Composition	Each Film Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No 5180 dated 06-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	

2710.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tomifen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Tamoxifen Citrate…10mg
	Diary No. Date of R& I & fee	Dy.No 5155 dated 06-02-2019 Rs.20,000/-
	Pharmacological Group	Anti-oestrogen
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(EQ 10MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	
	GMP status	Dated: 10-07-2019 **Concluding Remarks:** Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator.	Reference product is approved as Tamoxifen as citrate 10mg uncoated tablet.
	Decision: Deferred for the following : **Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. Tamoxifen as citrate 10mg uncoated tablet. Along with submission of requisite fee, master formulation & manufacturing method.**	
2711.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neoplaxol 100mg/5ml Injection
	Composition	Each 5ml ampoule contains: Etoposide as phospate…100mg
	Diary No. Date of R& I & fee	Dy.No 5592 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (5ml):As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	SEDOL 100MG/5ML INJECTION of Helix
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	

2712.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Irotec 300mg Injection
	Composition	Each ml contains: Irinotecan Hcl Trihydrate…20mg
	Diary No. Date of R& I & fee	Dy.No 5587 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Other antineoplastic agents
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (15ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	IRINOTECAN EBEWE 100MG/5ML of Novartis
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2713.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 80mg/2ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous 80mg polysorbate…80 qs 2ml
	Diary No. Date of R& I & fee	Dy.No 5589 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA Aproved in USFDA (40MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	TAXOTERE INFUSIONEACH VIAL CONTAINS DOCETAXEL TRIHYDRAT (AS ANHYDROUS) 80MG, POLYSORBATE 80PB Q.S TO 2ML of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision: Deferred for the following: • **Justification on scientific grounds for not performing terminal sterilization of applied formulation.**	

	• **Type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Status of Diluent whether it is combo pack or otherwise.**	
2714.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rubidox P 50mg/25ml Injection
	Composition	Each ml contains: Doxorubicin hydrochloride…2mg (as lposomalpegylated)
	Diary No. Date of R& I & fee	Dy.No 5607 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Anthracyclines and related substances
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(25ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2715.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 20mg/0.5ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous… 20mg polysorbate…80 qs 0.5ml
	Diary No. Date of R& I & fee	Dy.No 5595 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(0.5ml) vial: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	TAXOTERE I.V. INFUSIONE of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.**	

	• **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Submit separate application for diluent.**	
2716.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cisplat 50mg/100ml Injection
	Composition	Each ml contains: Cisplatin…0.5mg
	Diary No. Date of R& I & fee	Dy.No 5608 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Platinum compounds
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's (100ml vial): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	QUIRAL QUIMICA of NEOMEDIX RAWALPINDI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2717.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Menocar Tablets 2.5mg
	Composition	Each Film Coated Tablet Contains: Letrozole …2.5mg
	Diary No. Date of R& I & fee	Dy.No 5369 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	Rs.291.66/tablet, Rs. 8750/ 30tablets: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 18-10-2019 Certificate of GMP issued on 18-10-2019.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2718.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, KotLakhpat, Lahore
	Brand Name +Dosage Form + Strength	Virin 4 Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy.No 5334 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's,40's,50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM

	Me-too status	Revirin-C tablet of High-Q
	GMP status	Dated: 27-08-2018, 05-10-2018, 06-11-2018 **Recommendations:** The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2719.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 200mg Tablets
	Composition	Each Tablet Contains: Acyclovir…200mg
	Diary No. Date of R& I & fee	Dy.No 5802 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Anti viral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Clovir 200 mg Tablets of Glitz Pharam, Kahuta Road P.No.265, Industrial Triangle, Islamabad
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2720.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 800mg Tablet
	Composition	Each Tablet Contains: Acyclovir…800mg
	Diary No. Date of R& I & fee	Dy.No 5804 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,15's,20's,25's,30's: As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Virocyc Tablets of Global Pharmaceuticals
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2721.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 400mg Tablet
	Composition	Each Tablet Contains: Acyclovir…400mg
	Diary No. Date of R& I & fee	Dy.No 5803 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Cyclor Tablets of Candid Pharmaceuticals,
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2722.	Name and address of manufacturer / Applicant	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan-75700
	Brand Name +Dosage Form + Strength	Ovara 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 5902 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5

	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 11-05-2018 **Conclusion:** Based on the areas visited, people met and commitment of the firm for continuous improvement. It is concluded that the firm is operating at a **Good level of GMP compliance** at the time of inspection.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2723.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 250mg
	Composition	Each dispersible tablet contains: Deferasirox…250mg
	Diary No. Date of R& I & fee	Dy.No 6958 dated 19-02-2019 Rs.20,000/-
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	Dated: 20-09-2017 Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2724.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 500mg
	Composition	Each dispersible tablet contains: Deferasirox…500mg
	Diary No. Date of R& I & fee	Dy.No 6957 dated 19-02-2019 Rs.20,000/
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	ODEROX -500 DISPERSIBLE TABLET of M/S. AJ MIRZA PHARMA (PVT) LTD.,
	GMP status	Dated: 20-09-2017

		Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2725.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oxy Z 500mg Capsule
	Composition	Each Capsule Contains: Hydroxyurea…500mg
	Diary No. Date of R& I & fee	Dy.No 8123 dated 25-02-2019 Rs.20,000/-
	Pharmacological Group	Antimetabolite
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	1's, 10's, 1000's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	HYDAB 500MG CAPSULE of ATCO PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of required manufacturing facility.	

Case no. 03 Registration applications of import cases

b. New Cases (Human)

2726.	Name and address of Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. House # 166-A, Street # 9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name and address of marketing authorization holder	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No. 31977 dated 25-09-2018 Rs.100,000/- Dated 25-09-2018
	Fee including differential fee	Rs.50,000/- Dated 21-05-2018
	Brand Name +Dosage Form + Strength	Calderol 1mcg/ml Solution for IV Injection
	Composition	"Each ml Contains: Calcitriol……..1mcg"
	Finished Product Specification	Manufacturer's specifications
	Pharmacological Group	Vitamin D analogue
	Shelf life	36 months as per the stability study data of the product conducted as per conditions of zone IV-B
	Demanded Price	As per SRO

	Pack size	As per SRO
	International availability	Approved in USFDA
	Me-too status	
	Detail of certificates attached	CoPP (No. 2018/2203) issued by Turkish medicines and medical devices agency dated 04-06-2018 for calderol 1mcg/ml solution for IV injection which confirms the free sale status of the product in country of origin as well as GMP status of the manufacturer. The certificate was valid till 04-06-2020.
	Remarks of the Evaluator	
	Decision: Approved as per the policy for inspection of manufacturer abroad. Firm will provide valid, legalized CoPP before issuance of Registration letter.	

Case No. 04 Registration applications of drugs for which stability study data is submitted

b. Verification of stability study data

2727.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Sofosbuvir Tablet 400mg
	Composition	Each film coated tablet contains: Sofosbuvir…. 400mg
	Diary No. Date of R& I & fee	R&I date: 27-08-2018 Fee 20,000/- (20-08-2018) Duplicate dossier
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	28's(HDPE bottle): As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	N/A

STABILITY STUDY DATA			
Drug	Sofosbuvir Tablet 400mg		
Name of Manufacturer	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.		
Manufacturer of API	Optimus Drugs PVT Limited, Factory, Sy No. 239 & 240 Dothigudam(V) Pochampally(M), Nalgonda Dist., Telangana, India		
API Lot No.	**Batch No.**OP-GLD/10/15/037		
Description of Pack (Container closure system)	28's; HDPE Bottle		
Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real Time: 0,4,8,12,24 MonthsAccelerated: 0,4,8,12,24 Months		
Batch No.	Tr-01	Tr-02	Tr-03
Batch Size	212 tablets	212 tablets	212 tablets
Manufacturing Date	August, 2017	August, 2017	August, 2017
Date of Initiation	22th August, 2017	22th August, 2017	22th August, 2017
No. of Batches	03		
Date of Submission	28-06-18		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr.#	Documents To Be Provided	Status
17.	COA of API	Firm has submitted copy of COA stating following information on it: **Product:**Sofosbuvir **Batch No.**OP-GLD/10/15/037 **Manufacturer:**Optimus Drugs PVT Limited,
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted GMP certificate having following information on it: **Certificate No.**L.Dis.No.20121/A3/2018 **Issued to:**Optimus Drugs PVT Limited, **Issued on:** 21-05-2018 **Validity:** One Year From The Date Of Issue
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice stating following information on it: **Invoice No.** 412/EXP **Batch No of API.** OP-GLD/10/15/037 **Attested by Assistant Director (I & E) DRAP Karachi On** : 03-02-2016
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

SOFOSBUVIR TABLET 400MG, M/S ZAFA PHARMACEUTICALS LABORATORIES.

Following panel of inspectors visited M/s Zafa Pharmaceuticals Laboratories for verification of authenticity of submitted stability study data for registration of Sofosbuvir 400mg Tablet.

1. Syed Adnan Rizvi Director, DTL, Karachi.
2. Dr. Najam-us-Saquib Additional Director DRAP, Karachi.
3. Kirshan, Assistant Director, DRAP, Karachi.

Q.No.	Question	Observation by panel
37.	Do you have documents confirming the import of API including approval from DRAP?	The firm has imported Sofosbuvir from Optimus Drug Pvt. Ltd. Hyderabad INDIA, Supplier IRIS Karachi. Invoice No.412/EXP dated 15-11-2015. Batch # OP-GLD/10/15/037. The total quantityofAPI purchased was1.00 kg.The approval from DRAP is available. (Annex-A)
38.	What was the rationale behind selecting the particular manufacturer of API?	Rationale behind selecting the particular manufacturer of API, as it is GMP compliant and vendor evaluation has been done. (Annex-B).
39.	Do you have documents confirming the import of reference standard and impurity standards?	The reference standard & impurity standard were imported through Optimus Drug Pvt. Ltd. Hyderabad INDIA. In House Reference standard, Batch # OP-

		SFS/RS1402, quantity100mg.Impurity standard, Batch # OP-GLD/St-I/Rp-Isomer/A0453/055, with quantity 10.0mg. (Annex-C)
40.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has COAs for API, reference standards and impurity.
41.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP Certificate of API manufacturer issued by Drug Control Administration Govt. of TelanganaINDIA.L.DisNo. 2021/A3/2018 Dated 21-05-2018.
42.	Do you use API manufacturer method of testing for testing API?	The Firm has used manufacturer's method of testing for the testing of API.
43.	Do you have stability studies reports on API?	The firm has manufacturers Stability studies report of API.
44.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing as per SIM method and degradation products has been quantified by the API manufacturer.
45.	Do you have method for quantifying the impurities in the API.	The firm has used HPLC method for chromatographic impurities that was used for assay purpose.
46.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some quantities of API (As reference), reference standard.
47.	Have you used pharmaceutical grade excipients?	The firm has used Pharmaceutical grade excipients
48.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
49.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records of the excipient used.
50.	Do you have written and authorized protocols for the development of applied product?	The firm has written protocol for the development of Sofosbuvir Tablets 400 mg.(Annex-D)
51.	Have you performed Drug-excipient compatibility studies?	The firm has not performed drug excipient compatibility studies because the composition of their tablets/product is similar to that of the innovator's product (Sovaldi Tablets)
52.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies and their product show comparable dissolution profile and same were reviewed at time of inspection.
53.	Do you have product development (R&D) section.	The firm has separate new product development (R&D) section.
54.	Do you have necessary equipments available in product development section for development of applied product?	The firm has used Quality Control Lab instruments for the development of Sofosbuvir Tablets 400 mg. The firm has all necessary equipment in QC and Product development section.
55.	Are the equipment in product development section qualified?	All the equipment used in the development of product is qualified.
56.	Do you have proper maintenance / calibration / requalification program for the equipment used in PD section?	The firm has proper maintenance and calibration for the equipment used in quality Control for the development of the product.
57.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff for the development of the product with proper knowledge and training in product development. (Annex-E)
58.	Have you manufactured three stability batches for the stability studies of applied products required?	The firm has manufactured three stability batches, of Sofosbuvir Tablets 400 mg, TR01, TR02, TR03.

59.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability of batches are the number of tablets as per requirement of testing.
60.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. All the log books are properly maintained and reviewed at the time of inspection.
61.	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of the stability batches.
62.	Do you have developed and validated the method for testing of stability batches?	Yes, the firm has used manufacturer's method of testing, the method is validated.
63.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
64.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, the firm has proper documents confirming the qualification of equipment and instruments being used in the test and analysis of API and the finished product.
65.	Do your method of analysis stability indicating?	Yes the method of analysis is stability indicating.
66.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR compliant.
67.	Can you show Audit Trail reports on Stability study testing?	The firm showed the Audit trail report on API and finished product testing.
68.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
69.	Do you have commitment batches kept on stability testing?	The firm has three commitment batches kept on stability testing for real time stability studies.
70.	Do you have valid calibration status for the equipment used in Production and analysis?	Yes, the firm has valid calibration status for the equipment used in the production and analysis of Sofosbuvir Tablets 400 mg.
71.	Do proper and continuous monitoring and control are available for stability chambers.	Continuous power supply and monitoring and control are available for the stability chambers.
72.	Do related manufacturing area, equipment, personal and utilities be used as GMP compliance	The relevant manufacturing facilities are GMP complaint.

Conclusion:

M/s Zafa Pharmaceutical Laboratories was inspected as per directions contained in DRAP letter No. 13-11/2017-PEC (Pt) dated 30th July, 2019. During inspection, the panel inspected/reviewed the relevant record, data and premises in detail with specific focus on the observations/points made in above referred letter. Following are the current observations:

5. **Criterion/reference for selection of Q Value 70%:** - The said molecules was not included in any official monograph, therefore, the firm previously performed the dissolution test as per general requirement for dissolution testing and there was no any specific criteria for the selection of Q value 70%. Now, the firm have performed dissolution test for their product according to US-FDA recommended dissolution method and found it satisfactory at the time of inspection.
6. **Valid GMPCertificate** of API Manufacturer is hereby attached for reference.
7. On the basis of risk-based approach the genuineness/ authenticity of stability data submitted by the firm for registration of Sofosbuvir Tablets 400mg is verifiable to satisfactory level.
8. The related manufacturing area, equipment, personnel and utilities observed in line as per GMP requirements and well suited for manufacturing of the said product.

Recommendations:

Based on the people met, documents reviewed and observations made during inspection including corrective action taken by the firm, the panel unanimously recommends that the firm may kindly be granted necessary registration of Sofosbuvir Tablets 400mg.

Decision(M-294): Registration Board decided to defer the case for following submissions:

- Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.
- Valid GMP certificate of the API manufacturer.

Now the applicant has submitted following:
Applicant has referred to their Comparative dissolution profile of applied formulation with reference product and submitted results declaring drug release profile of applied formulation is greater than 90 % within 15 minutes.

Decision: Registration Board keeping in view its decision taken in 293rd meeting decided to defer the case for following submissions:

- **Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.**
- **Valid GMP certificate of the API manufacturer.**

2728.	Name and address of manufacturer / Applicant	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.
	Brand Name +Dosage Form + Strength	Helisopt Ophthalmic Suspension
	Composition	Each ml ophthalmic suspension contains: Brinzolamide...……..…10mg Timolol (as maleate)…….5mg
	Diary No. Date of R& I & fee	Duplicate dossier
	Pharmacological Group	Carbonic Anhydrase Inhibitor, Beta-adrenergic blocking agent.
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP compliant dated 10-08-2017.

STABILITY STUDY DATA

Drug	Helisopt Ophthalmic Suspension		
Name of Manufacturer	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.		
Manufacturer of API	**Timolol (as maleate):** M/s. Gangwal Chemicals Pvt. Ltd., Plot No. N-5 Mide, TarapurBoisar, District: Thane 01 506, India **Brinzolamide:** M/s. Century Pharmaceuticals 103 to 106, GIDC, Halol, 389 350, Dist: PANCHMAHAL, Gujrat State, India.		
API Lot No.	**Timolol (as maleate):** (Batch No. TMM-051656. Mfg date: May 2016, Quantity: 2kgs). **Brinzolamide:** (Batch No.07111004-BA. Mfg date: March 2016, Quantity: 80grams).		
Description of Pack (Container closure system)	(5ml) LDPE bottle		
Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) Accelerated: 0,3,6 Months		
Batch No.	TF 001	TF 002	TF 003
Batch Size	01 Litters	01 Litters	01 Litters

Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	25-08-2017	25-08-2017	25-08-2017
No. of Batches	03		
Date of Submission	Dy No.12219, 03-04-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
25.	COA of API	Yes
26.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Timolol (as maleate):** Copy of GMP certificate bearing a number NEW-WHO-GMP/CERT/KD/50623/2016/11/17467 issued to M/s. Gangwal Chemicals by Food & Drug Administration Maharashtra, India. Valid until 02-12-2018. **Brinzolamide:** Copy of GMP certificate bearing a number 1707219 issued to M/s. Century Pharmaceuticals by Food & Drug Control Administration, Gujarat state India. Valid until 06-07-2019.
27.	Protocols followed for conduction of stability study and details of tests.	Yes
28.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
29.	Documents confirming import of API etc.	**Timolol (as maleate):** Copy of Form 5 (license to import Drugs) issued by ADC, DRAP, Karachi dated 04-07-2016 has been submitted. Copy of commercial invoice has been submitted. **Brinzolamide:** Copy of Form 6 (license to import Drugs for clinical trial examination) issued by ADC, DRAP, Karachi dated 21-09-2016 has been submitted. Copy of ADC attested commercial invoice has been submitted.
30.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
31.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
32.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR & REPLIES OF APPLICANT

- The firm has claimed Manufacturer's Specifications and the product is not present in available USP & BP.
- Submit raw data sheets of analytical method of applied formulation.
- Commitment to follow Drug Specification Rules, 1978.
- Commitment to continue real time stability studies till the proposed/assigned shelf life.
- Latest GMP inspection report conducted within the period of last one year.
- Chromatographic conditions in the finished product testing method submitted in dossier is different to that submitted with stability studies. Clarify/Justify.

Applicant has submitted that "We have applied for product dossier file on 20-04-2012, at that time, we did not have HPLC complies Software 21CFR but now we have all HPLCs complies with software 21CFR and we are working on HPLC with software 21CFR for new product's stability studies. Therefore you found the

difference in chromatographic conditions & current chromatographic conditions upon which stability studies are performed are following: wavelength 280nm & flow rate 1ml/minute".

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Helisopt Ophthalmic Suspension (Brinzolamide/Timolol) by M/s. Helix Pharma , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 10th December, 2018.
Investigation Date and Time: 18th December, 2018 (Forenoon).
Investigation Site: Factory premises of M/s. Helix Pharma, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Helix Pharma, Karachi for registration of Helisopt Ophthalmic Suspension each ml of which contain Brinzolamide 10mg and Timolol (as maleate) 5mg and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

4. Dr. Abdul Waheed, Assistant Director, CDL, DRAP, Karachi
5. Mr. Adnan Rizvi, Director DTL Sindh, Karachi (Member Registration Board)
6. Dr.Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Helisopt Ophthalmic Suspension

S.No.	Question	Observation by panel
1	Do you have documents confirming the import of API ?	The firm has imported 80g Brinzolamide from M/s Century Pharmaceuticals Limited, India vide invoice no. EXP16087 dated 2-09-2016 and 4.0 kg from M/s Gangwal Chemical Pvt. Ltd. India vide invoice No. EXP-T/030/16-17 dated 05.01.2017 and obtained approval from DRAP Karachi
2	What was the rationale behind selecting the particular manufacturers of APIs?	There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF etc. The firms were evaluated on above mentioned criteria and selected
3	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of both APIs USP reference standard and impurity standards.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs, working standards and their impurities.
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of Brinzolamide and timolol manufacturers issued by Food and Drug Control Administration, Gujrat State, India and Food and Drug Administration, Mahrashtra, India respectively.
6	Do you use API manufacturer method of testing?	The firm has used USP method of testing for both APIs.
7	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months on both APIs and five years and four years real time stability studies reports on the Brinzolamide and Timolol respectively.

<table>
<tr><td>8</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>The stability testing has been performed as per SIM method and degradation products have been quantified.</td></tr>
<tr><td>9</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm has USP method for quantifying the impurities in the API.</td></tr>
<tr><td>10</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has remaining quantities of API and reference standard of both APIs.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has documents confirming the procurement of all excipients used.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of API ophthalmic suspension?</td><td>The firm has written and authorized protocols for the product development.</td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>N/A</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with equipment for manufacturing of ophthalmic suspension dosage form. The analytical part is performed on equipment of routine quality control tests.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of API ophthalimic suspension?</td><td>The firm has necessary equipment for product development of API ophthalmic suspensions. The product in question has been developed while using some equipment of commercial manufacturing also. Furthermore, the analytical part has been performed via the routine quality control equipment. Firm has already placed orders for procurement of other equipment for this section.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff which include One Chemist and One Pharmacist in product development section with relevant work experience.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of API ophthalmic suspension as required?</td><td>The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Helisopt ophthalmic suspension packed in LDPE bottles of 5ml each.
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg Date</td></tr>
<tr><td>TF 001</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 002</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 003</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
</table></td></tr>
<tr><td>23</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of bottles per testing and the number of bottles required for whole stability testing.</td></tr>
</table>

24	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.
25	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches in which the stability conditions are: Real Time: 30°C and 65% RH Accelerated: 40°C and 75% RH, however, the firm has used LDPE container for the product in question for which ICH guidelines and WHO recommends 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies.
26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches. The method is supported by impurities standards spiking studies, forced degradation, hence capable of quantifying the degradation products in their ophthalmic suspension kept on stability testing.
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
28	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
30	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 12 months studies have been completed with satisfactory results.
34	Do you have valid calibration status for the equipment used in API ophthalmic suspensions production in analysis?	The firm has valid calibration status for the equipment used in helisopt ophthalmic suspension production and analysis.
35	Do proper and continuous monitoring and control are available for stability Chamber?	Continuous power supply and monitoring are available for stability chambers.
36	Do related manufacturing area, equipment, personnel and utilities be Rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.

Discussion:

6. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Helisopt Ophthalmic Suspension is verifiable to satisfactory level.
7. Furthermore, the firm has conducted the stability studies as per their protocol which is 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies, whereas, the recommended stability conditions for products packed in semi-permeable containers are 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. However, 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies may be used for semi-permeable

containers provided the calculated water loss multiplied with the corresponding factor may not exceed 5% of initial, which is considered as significant change.

8. In this case the firm has not calculated water loss at any stage, so no comparison can be made between the reference and alternative relative humidity as mentioned in ICH Q1A (R2) (2.2.7.3. Drug products packaged in semi-permeable containers).
9. On risk-based approach the data evaluated during inspection does not show any deviation in the critical tests throughout the study period which may be altered if the water has lost more than the prescribed limits.
10. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Helisopt Ophthalmic Suspension.

Recommendations:

The firm may be granted necessary registration of Helisopt Ophthalmic Suspension in their name with the direction to conduct stability studies on their commitment batches as per ICH guidelines i.e. 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies and submit the data to the Drug Registration Board.

Previous Decision:

Registration Board in its 287th meeting decided as follow:

Registration Board deferred the case for submission of stability data at next time point of long term stability studies along with assessment of water loss rate for applied container closure system as per ICH Q1A (R2) guidelines for "Stability Testing of New drug substances and products."

Evaluation by PEC:

Applicant has submitted results of Water loss test in the form of graphs conducted on following newly manufactured batches of applied formulation.

Sr. No.	Batch No.	Batch Size.
1.	TF004	90 bottles
2.	TF005	90 bottles
3.	TF006	90 bottles

Decision:

Deferred for submission of formula by which results of moisture loss from the semipermeable container are calculated as well as submit details of readings used to plot the graph, as only graphs are submitted.

Evaluation by PEC:

Now the applicant has submitted following:

3. Formula by which results of moisture loss from the semipermeable container are calculated.
4. Readings used to plot the graph with the conclusion that moisture loss from the semipermeable container is within permissible limits.

Decision: Registration Board decided to approve registration of "Helisopt Ophthalmic Suspension" by M/s Helix Pharmaceuticals. Manufacturer shall place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data (Deferred cases)

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1862.	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.	Tigrelor 90mg tablet Each film-coated tablet contains:	Form- 5 Dy.No.931 Dated: 22-12-2014 Rs.50,000/-	Brilinta 90 mg film-coated tablets of M/s AstraZeneca UK Limited (MHRA Approved) / Not applicable

		Ticagrelor...90mg (Platelet Aggregation Inhibitor) Innovator's specifications	(17-12-2014) 2 x 10's; as per SRO	Last GMP inspection was conducted on 12-12-2017 and GMP certificate was issued on 15-12-2017.

STABILITY STUDY DATA			
Drug	Tigrelor 90mg tablet		
Name of Manufacturer	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-TG-201709061		
Description of Pack (Container closure system)	Alu- Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (month) Real Time: 0, 3, 6, 9, 12 (months)		
Batch No.	17PD064TICT05	17PD081TICT06	17PD089TICT07
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Nov-2017	Dec-2017	Dec-2017
Date of Initiation	29-01-2018	29-01-2018	30-01-2018
No. of Batches	04		
Date of Submission	16-08-2018 (27937)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
17.	CoA of API	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes

24.	Commitment to follow Drug Specification Rules, 1978.	Yes
REMARKS OF EVALUATOR		
Firm has submitted 6 months accelerated and 12 months real time stability study data of four batches.		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: Date of submission: 02-07-2019 vide diary no. 10339		
Administrative Portion		
39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Apixa 2.5mg and 5mg (Apixaban) Tablets", which was presented in 289th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Pharmatec Pakistan (Private) Ltd, Karachi. Date of inspection: 30-04-2019 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
40.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
41.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted COAs of following working standards & impurity Standards : Ticagrelor working standard (B # WS201603001) Ticagrelor working standard (B # WTG01-170401) Impurity standards TG16 WRS (B# WTG05-170401) De-Ethoxyl of TG WRS (B# WTG06-170401)
42.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
43.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for evaluation of vendors.
44.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
45.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product
46.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
Production Data		
47.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of "Protocols/SOP for the Development of Ticagrelor 90mg Tablet".
48.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:

Batch No.	Batch Size	Mfg. Date
17PD064TICT05	2500 Tablets	29-01-2018
17PD064TICT06	2500 Tablets	29-01-2018

<table>
<tr><td></td><td></td><td><table><tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>30-01-2018</td></tr></table></td></tr>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td><table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>1800 Tablets</td><td>700 tablets</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 29-11-2017 to</td></tr>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Ticagrelor.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ticagrelor 90mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Nantong Chanyoo Pharmatech Co., Ltd. China. The storage conditions for real time stability data are 25±2ºC/60±5%RH.</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>The compatibility of Ticagrelor 900mg (API) and 40mg Sodium lauryl sulphate (Excipient) was studied by HPLC analytic techniques after storage of mixture under accelerated conditions. HPLC analysis of these mixtures has not shown any significant physical and chemical instability. Hence the study concludes that Ticagrelor and sodium lauryl sulphate are compatible.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Ticagrelor 90mg tablet and Brilinta 90mg tablet. The results suggest similarity factor (f2) > 50 and difference factor (f1) < 15 in all three media.</td></tr>
<tr><td>57.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of “Ticagrelor 90mg Tablet” from.</td></tr>
<tr><td colspan="3"><table>
<tr><th>Sr. No.</th><th>Observations communicated</th><th>Response by the applicant</th></tr>
<tr><td>9.</td><td>Digital data logger record does not cover the duration of stability study data. Clarification is required.</td><td>Digital logger sheets which cover the duration stability study data.</td></tr>
</table></td></tr>
</table>

10.	Justification is required for preparation of four batches for the purpose of carrying out stability studies.	The first batch exhibiting the batch number 17PD048TICT04, is the pre-formulation batch, the very initial batch developed at every step of formulation development, this supports in making decision. These steps include process feasibility studies, formulation optimization and manufacturing process.
11.	Audit trail reports of only one date are submitted. It is important to submit the audit trail reports at all time points of stability studies as well as comparative dissolution study.	Audit trail on the testing time point is submitted.
12.	Polymorphic formof Ticagrelor API is required to be submitted.	The firm has submitted that polymorphic form-II was used and further stated that same form of molecule is discussed in the patent of Astra Zeneca. The form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction.

Storage conditions under which stability studies were conducted are at 25ºC±2ºC/60%±5% RH.
Previous Decision: Deferred for submission of scientific justification for conducting API stability studies at storage conditions of 25ºC±2ºC/60%±5% RH.
Evaluation by PEC: The firm has submitted that internationally API stability studies are conducted at 25ºC±2 ºC/60%±5%RH because majority of API manufacturer supplies their product to international market. When we receive APIs, we keep them in controlled temperature i.e., 25ºC. When we manufacture our finished product with these APIs, we use to conduct stability studies of our products according to our stability Zone i.e., Zone IVA.

Previous Decision: Registration Board deferred the case for submission of valid GMP certificate of M/s Nantong Chanyoo, Jiangsu province, China, issued by relevant Provincial or state Regulatory authority since the Nantong Food and Drug Administration is not the relevant provincial regulatory authority (M-293).
Response of the firm: Firm has submitted copy of "License for Drug production" issued by the Jiangsu Food and Drug Administration in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., China with License number "S. 20160512" and valid upto 31-12-2020.
The above cited certificate has been verified from the following web link of National Medical Product Administration of China:
http://app1.sfda.gov.cn/datasearchcnda/face3/base.jsp?tableId=34&tableName=TABLE34&title=%D2%A9%C6%B7%C9%FA%B2%FA%C6%F3%D2%B5&bcId=152911762991938722993241728138 .

Deferred for following submissions (M-294):

- Submission of real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product as per the decision of 290th meeting of Registration Board since the firm has used API whose stability testing has not been done as per the conditions of Zone IV-A.
- Scientific justification for performance of drug excipient compatibility studies with only 1 excipient (i.e. Sodium lauryl sulphate).
- Status whether form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction by M/s Pharmatec or API manufacturer

Evaluation by PEC: The firm has submitted following:

- Stability study data of API as per Zone IV-A.
- Drug Excipient compatibility was conducted and assessed through HPLC. Binary mixtures of excipient and drug substance at a ratio 1:1 ratio in the solid state were prepared. Results showed no interference/degradant was detected with any of the excipient used.
- Crystalline Form-II of Ticagrelor is confirmed by melting points & X-Ray diffraction as per DMF of API manufacturer.

Decision: Registration Board decided to approve registration of Tigrelor 90mg Tablet with Innovator's specifications by M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi. Manufacturer will place

first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
1863.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Tofacit 5mg Tablet Each Film Coated tablet Contains: Tofacitinib (as citrate) ……5mg Selective immunosuppressants ATC code: L04AA29	Form-5 Dy. No. 34109: 15.10.2018 PKR 20,000/-: 04.08.2018 As per SRO	XELJANZ 5 mg film-coated tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

Case history:
Decision of 290th meeting of Registration Board:
Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies and generic / me-too status which were adopted by the Registration Board in its 275th meeting.

Now the firm has submitted the reference and generic evidence which is as under:
Reference status "XELJANZ 5 mg film-coated tablets (Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium"
Generic/me-too status " Xeljanz Film Coated Tablet 5mg of M/s Pfizer"
Decision of 293rd meeting of Registration Board:
Deferred for further deliberation regarding stability data.

The stability data of 3 batches have been submitted by the firm

STABILITY STUDY DATA

Manufacturer of API	Kaifeng Pharmaceutical (Grp)Co. Ltd. No. 1 Yunan Street Kaifeng		
API Lot No.	KFX171203		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	11-2018	12-2018	12-2018
Date of Initiation	14-11-2018	20-12-2018	20-12-2018
Date of submission	4648 (16-03-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes

Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number 783242202418.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 15-10-2018 specifying import of 0.5g API. The invoice is not signed by AD (I&E) DRAP Karachi. Firm has submitted copy of DHL invoice for the said invoice having tracking number 783242202418.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted GMP certificate (No. HA20150067) issued by CFDA China. The certificate is valid till 16-11-2020.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.

6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 70 Tablets TF-02: 98 Tablets TF-03: 108 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated stability studies & long term stability studies reports of three batches of API.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of their product against the Xeljanz Tablet. The drugs show more than 85% release in 15 minutes at all media.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Submit protocols for stability studies	Firm has submitted protocols for stability studies.
You have provided dissolution specifications as NLT 75% in 15 minutes without specifying the value of "Q".	Firm has submitted revised dissolution specifications with acceptance criteria NLT 75%(Q) after 15 minutes
Submit stability study data of API	Firm has submitted the stability study data of API for three batches.

Decision: Registration Board decided to approve registration of Tofacit 5mg Tablet (Tofacitinib, Selective immunosuppressants, ATC code: L04AA29) with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case no. 05: Registration applications of locally manufacturing drugs (human) submitted on CTD format

1864.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18270 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..12.5mg Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 12.5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: M/s. Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ^{o}C ±2^{o}C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30^{o}C±2^{o}C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1865.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18269 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1866.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18268 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 12.5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 12.5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 12.5mg + 500mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1867.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20014 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg

		Metformin hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 5mg /1000mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	Empozin-M 5mg + 1000mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ºC ±2ºC & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ºC ±2ºC & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30ºC±2ºC & 75%±5% RH).

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1868.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.20013 : 08-10-2019
	Details of fee submitted	PKR 50,000/-: 08-10-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..850mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	---------
	The status in reference regulatory authorities	Synjardy 5mg /850mg tablet of BOEHRINGER INGELHEIM (USFDA approved)

	For generic drugs (me-too status)	Empozin-M 12.5mg + 850mg tablet of Macter
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 °C ±2°C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 °C ±2°C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30°C±2°C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in o.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1869.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (pvt.) Ltd., F-95, Off, Hub River Road, S.I.T.E, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of GMP certificate granted based on the inspection dated 28-08-2019.
	Evidence of approval of manufacturing facility	The firm has provided Tablet General section as per document of licensing Regularization of DML.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.18267 : 23-09-2019
	Details of fee submitted	PKR 50,000/-: 23-09-2019
	The proposed proprietary name / brand name	EMPOLI Plus 5 + 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……..500mg
	Pharmaceutical form of applied drug	Immediate release film coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	----------
	The status in reference regulatory authorities	Synjardy 5mg /500mg tablet of BOEHRINGER INGELHEIM (USFDA approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Empagliflozin: Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Empagliflozin: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 5 years at long term storage conditions (30 ^{o}C ±2^{o}C & 65%±5% RH). Metformin hydrochloride: The submitted stability study data was conducted at accelerated condition (40 ^{o}C ±2^{o}C & 75%±5% RH) for 6 months, 6 years at long term storage conditions (30^{o}C±2^{o}C & 75%±5% RH).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted results of comparative dissolution profile of their Batch No. TFB-T001 with the innovator product i.e. Xeljanz 5mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
STABILITY STUDY DATA		

Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co.,Ltd, Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City Liaoning Province -123000, China Metformin hydrochloride: M/s Wanbury Limited, 10th Floor, B-wing, BSEL techpark, Sector 30A, Navi Mumbai, India		
API Lot No.	Empagliflozin: Metformin hydrochloride:		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Strengths applied	Batch No	Batch size	Manufacturing date
EMPOLI Plus 12.5mg + 1000mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 1666 Tablets 1666 Tablets	November 2018 November 2018 November 2018
EMPOLI Plus 12.5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 12.5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	December 2018 December 2018 December 2018
EMPOLI Plus 5mg + 1000mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	January 2019 January 2019 January 2019
EMPOLI Plus 5mg + 850mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	January 2019 January 2019 January 2019
EMPOLI Plus 5mg + 500mg Tablet	Lab-01 Lab-02 Lab-03	2500 Tablets 2500 Tablets 2500 Tablets	November 2018 November 2018 November 2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years TEFOD *(Tenofovir Alafenamide)* 25mg Tablets on 28th January, 2019 by following panel: 1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board 2. Mr. Aslam Shah, Member Registration Board. 3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Empagliflozin: The firm has submitted copy of GMP certificate for M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020.

		Metformin hydrochloride: The firm has submitted copy of GMP certificate for M/s Wanbury Limited, Andhra Pradesh, India. The certificate is valid till 05-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Empagliflozin: Firm has submitted copy of invoice for the import of Empagliflozin (1kg) attested by AD (I&E) Karachi office dated 08-11-2018. Metformin hydrochloride: Firm has submitted copy of invoice for the import of metformin hydrochloride (1.5kg) attested by AD (I&E) Karachi office dated 25-05-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC

Shortcomings communicated	Response by the firm
Though you have submitted summary of batch analyses release results of the FPP manufacturer for relevant batches in quality overall summary, however it is not provided in relevant section of module 3	The firm has provided data of relevant section of Module 3.
Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) (Empagliflozin and metformin hydrochloride) shall be submitted as per section 3.2.S.4-Control of drug substance	The firm has submitted analytical method verification studies for both drug substances.
How it is possible even in the presence of stress conditions, no degradation/impurities were observed in specificity parameter of analytical validation of finished product. Please justify your findings.	The firm has submitted that selectivity of method can be determined by following two methods • Spiking of impurities • Forced Degradation We performed both methods and no degradation has been observed due to high stability of these molecules.
The justification of specification(s) for non-pharmacopeial products must be provided.	The firm has submitted that we have developed in-house justification for inclusion of tests non-pharmacopoeial.
Details of reference standards needs to be submitted since details of metformin impurity A and metformin impurity F are submitted without mentioning API reference standard. In case of Empagliflozin, working standard of API has been procured. Justify the quantity of working standard procured will it be sufficient for complete test and analysis.	The firm has submitted that assay of Metformin hydrochloride performed by titrimetric method hence working standard not required. While for testing of finished product, reference standard is used to standardize the working standard. The firm has submitted justification for quantity of working standard procured for test and analysis. Amount of working standard procured is 125mg. 125mg is used for analysis of API.

	125mg is used for standardization of in-house standard. 10mg working standard required for single analysis of finished product. No. of testing per strength is 6mg (60mg consumed). Total no. of testing per 6 strength is 36mg (360mg consumed).
Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	The firm has performed pharmaceutical equivalence of their test formulations with different strengths of Synjardy as below: • Synjardy 12.5/1000mg Tablets (Boehringer Ingelheim, Batch # 644963) • Synjardy 12.5/850mg Tablets (Boehringer Ingelheim, Batch # 544531) • Synjardy 12.5/500mg Tablets (Boehringer Ingelheim, Batch # 856310) • Synjardy 5/500mg Tablets (Boehringer Ingelheim, Batch # 856327) • Synjardy 5/850mg Tablets (Boehringer Ingelheim, Batch # 644574) • Synjardy 5/1000mg Tablets (Boehringer Ingelheim, Batch # 644648)
Though you have submitted brief summary of CDP with innovator in module 2, however the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed in relevant portion of module 3.	The firm has submitted performance of comparative dissolution test of their test formulations against innovator formulations in 3 different pH media i.e., 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8 for relevant section of module 3. The results show comparable dissolution with innovator's product

Decision: Registration Board decided to defer the cases for justification of using Titrimetric method alongwith performance of potentiometric end point for analysis of metformin API.

1870.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28418 : 27-12-2019

	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..50mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 50mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)
	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1871.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28419: 27-12-2019
	Details of fee submitted	PKR 20,000/-: 27-12-2019, 30,000/-: 18-08-2020
	The proposed proprietary name / brand name	D-Pain Tablet 75mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol as hydrochloride……..75mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Other opioids (N02AX06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NUCYNTA 75mg film coated tablets by COLLEGIUM PHARM **(USFDA** Approved)
	For generic drugs (me-too status)	----
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 12 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their developed product D-Pain 50mg with comparator product Tapento IR 75mg Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. The results of drug release were greater than 85% in 15 minutes in all medium therefore the firm did not calculate similarity factor *f*2 values.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA	
Manufacturer of API	M/s SYMED LABS LIMITED, (UNIT-VI), Survey No. 744, 745, 750, 751, 752, & 753, Mandollagudem (Village), Choutuppal (Mandal), Yadadri District-508252 Telangana, India.
API Lot No.	6TDL 0110318

Description of Pack (Container closure system)	Alu-Alu Blister 1×10's		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
	Batch No.	Batch size	Manufacturing date
D-PAIN 50MG TABLET	T-001 T-002 T-003	1500 Tablets	09-2018
D-PAIN 75MG TABLET	T-001 T-002 T-003	1000 tablets	09-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#JX170001) for M/s Symed Labs Limited, India issued by Drug Control Administration, Government of Telangana, India. It was valid till 24-04-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Dissolution conditions of innovator as per Biopharmaceutics Review:
Apparatus: Type I (Basket apparatus)
Spindle rotation: 75 RPM
Medium: 0.1 M HCl
Medium volume: 900ml
Time: 45 min
Acceptance criteria: NLT 80% (Q) of the labelled amount of Tapentadol (as HCl) dissolved in 45 min

Sr. No.	Observations communicated	Response by the firm
17.	Submit Quality Overall Summary (QOS) needs to be submitted as per 293rd meeting of Registration Board.	The firm has submitted summarised information of drug substance and drug product as per 293rd meeting of Registration Board
18.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Firm has submitted copy of commercial invoice specifying import of 2.0Kg of Tapentadol Hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad office dated 29-03-2018.
19.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	The firm has submitted copy of GMP certificate however it is expired now.
20.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
21.	Summary of batch analyses release results of the drug product manufacturer for relevant batch needs to be submitted as per 2.3.S.4.4 (b).	Submitted
22.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Tapento IR 75mg tablet. Unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., 50mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.
23.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	Submitted.
24.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted data of relevant modules.

Decision: Registration Board decided as follows:

- **To defer registration application of D-Pain 50mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **To approve registration of D-Pain 75mg tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.**

1872.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road,

		Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4211: 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020
	The proposed proprietary name / brand name	Asprala 81mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated delayed release tablet contains: Aspirin……..81mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Film coated delayed release Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent and proton pump inhibitor
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablets 81mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 81mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Andra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process

		and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Aspirin: The Firm has submitted 6months accelerated (40ºC ± 2ºC/75%± 5% RH) and 60months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches. Omeprazole: The Firm has submitted 6months accelerated (40ºC ± 2ºC/75%± 5% RH) and 48months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.
1873.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy panel inspection dated 24-12-2018 wherein renewal of DML was granted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 13th June, 2107 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4210 : 11-03-2020
	Details of fee submitted	PKR 20,000/-: 21-02-2020, 30,000/- 10-03-2020
	The proposed proprietary name / brand name	Asprala 325mg/40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Aspirin……..325mg (Delayed release) Omeprazole…….40mg (Immediate release)
	Pharmaceutical form of applied drug	Uncoated Tablet
	Pharmacotherapeutic Group of (API)	Antiplatelet agent (B01AC06)
	Reference to Finished product specifications	Innovators specifications
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	YOSPRALA Tablets 325mg /40mg by Arelez Pharmaceuticals (USFDA approved)
	For generic drugs (me-too status)	OMO/ASPER Tablets 325mg /40mg by M/s Helix
	Name and address of API manufacturer.	Aspirin: M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China Omeprazole: M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Aspirin:** The Firm has submitted 6months accelerated (40ºC ± 2 ºC/75%± 5% RH) and 60months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches. **Omeprazole**: The Firm has submitted 6months accelerated (40ºC ± 2 ºC/75%± 5% RH) and 48months real time (30ºC ± 2 ºC/60%± 5% RH) stability study data of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution study of their Batch No. TT-001 with the innovator product i.e. Yosprala 325/40mg Tablets. Firm has performed CDP in 0.1 N HCl, acetate buffer and phosphate buffer. Comparison of results indicate that omeprazole releases more than 85% in 10 minutes in pH 1.2 and 6.8, therefore calculation for *f2* factor was not made. However, for aspirin F2 factor is 58.42, hence dissolution profile of both products found comparable.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method.

STABILITY STUDY DATA

Manufacturer of API	**Aspirin:** M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China **Omeprazole:** M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India		
API Lot No.	**Aspirin:** 171315 **Omeprazole:** OME/E-222/16		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	Batch size	Manufacturing date
ASPRALA 81MG/40MG TABLET	TT-001 TT-002 TT-003	13000 Tablets 13000 Tablets 13000 Tablets	06-2018 06-2018 06-2018
ASPRALA 325MG/40MG TABLET	TT-001 TT-002 TT-003	1500 Tablets 1500 Tablets 1500 Tablets	09-2019 09-2019 09-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to last onsite panel inspection for instant dosage form conducted during last two years Promig plus Tablets on 13th & 14th March, 2019 which confirms that : HPLC is 21 CFR II compliant. Digital data loggers were available for continuous monitoring of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Aspirin:** The firm has submitted copy of GMP certificate for M/s Shangdong Xinhua Pharmaceutical Co. Ltd. 14 Dongyi Road, Zhangdian District, Zibo city, Shangdong province, China issued by Shangdong Food and Drug

		Administration. It is valid till 18-10-2022. **Omeprazole:** The firm has submitted copy of GMP certificate for M/s Everest Organics Limited, Sadasivpet (Mandal) Medak, Telangana, India issued by Government of Telangana, Drugs Control administration. It was valid till 31-03-2017.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** Firm has submitted copy of commercial invoice specifying import of 5Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office dated 11-06-2018. **Omeprazole:** Firm has submitted copy of commercial invoice specifying import of 100Kg of Aspirin. The invoice is attested by AD (I&E) DRAP Islamabad office dated 13-05-2016.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

Sr. No.	Observations communicated	Response by the firm
13.	Evidence of import of API including copy of commercial invoice cleared by DRAP field office.	Evidence of import of both APIs attested by AD (I&E), Islamabad is submitted
14.	GMP certificate of API manufacturer issued by regulatory authority of country of origin needs to be submitted.	Valid GMP certificate for omeprazole is yet to be submitted.
15.	Provide certificate of analysis of each batch of API used in the stability studies of the three submitted batches.	Submitted
16.	Provide data of pharmaceutical equivalence against innovator product including data of comparative dissolution profile to justify your formulation development as per the requirement of section 3.2.P.2.2.1.	The firm has submitted that we performed pharmaceutical equivalence against comparator product that is Yosprala 325mg/40mg tablet. But unfortunately we are unable to arrange innovator pack / comparator of one of its strength i.e., Yosprala 81mg/40mg Tablet. Being same dosage form and same kind of release profile of both strengths, the firm has requested to accept the study of higher strength of same product against it lower strength also.

17.	Submit data to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	The firm has submitted analytical method validation studies.
18.	The drug substance and drug product part of Module III needs to be submitted as per 293rd meeting of registration covering all the sections mentioned in that document.	The firm has submitted details of drug substance and drug product as per 293rd meeting of Registration Board.

Decision: Registration Board decided as follows:

- **to defer registration application of Asprala 81mg/40mg Tablet for submission of pharmaceutical equivalence and comparative dissolution profile with innovator / comparator product of same strength.**
- **to approve registration of Asprala 325mg/40mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Manufacturer will also perform process validation studies on first three commercial batches as per the commitment submitted along with registration application.**

Item No. : Agenda of Evaluator AD PEC-I

Item No. I: Registration Applications for Local Manufacturing of (Human) Drugs
a. New Cases

2360.	Name and address of manufacturer / Applicant	M/s Skim Pharmaceuticals 10/B value addition city Faisalabad
	Brand Name +Dosage Form + Strength	SKIFENAC Diclofenac Sodium 50mg sustain coated pellets
	Diary No. Date of R& I & fee	Each capsule contains: Diclofenac sodium sustained release pellets….50mg Source of Pellets: M/s Vision Pharmaceutical Islamabad
	Composition	Dy. No. 20075 dated 04-06-2018 Rs20,000/-Dated 04-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20,s capsule in Alu/PVC Blister & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac sodium 25mg & 50mg) gastro resistant **Tablet** by M/s Daxcel Pharma, MHRA Approved.
	Me-too Status	Lifdik 50mg capsule by M/s Goodmann, Reg No. 52586
	GMP Status	DML No. 000830 issue dated 03-12-2015 Panel recommended additional sections including Capsule (general) dated 19-01-2018
	Remarks of the Evaluator-I	The firm initially applied for Sustained Release Capsule and then it was revised as Enteric coated Capsule as per reference product and submitted fee Rs. 5,000/- vide challan number 0300788 dated 13/04/2020.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2361.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 1.5mg Tablet

	Diary No. Date of R& I & fee	Dy.No 38171 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…….1.5mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's, Rs. 1000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 1.5mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. No. 079270
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2362.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 9mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38174 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…9mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5D
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 4000/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	• The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system. • Me too status could not be confirmed.
	Decision: Deferred for; • **Clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2363.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38173 dated 20-11-2018 Rs.20,000/- Dated

	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone…6mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 2700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Avega 6mg Tablets by M/s Biogen Pharma, Reg No. 080370
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2364.	Name and address of manufacturer / Applicant	M/s AGP Limited, B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Paliga XR 3mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38172 dated 20-11-2018 Rs.20,000/-
	Composition	Each Film Coated Extended Release Tablet Contains: Paliperidone……3mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	14's price Rs. 1700/-
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets 1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 3mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. no. 079271
	GMP Status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator-I	The reference product Invega, approved by USFDA is prolonged release tablet manufactured by OROS Push-Pull Technology and the public assessment report describes that osmotic pressure delivers paliperidone from the dosage form at a controlled rate. While the firm has stated that the product will be manufactured with simple matrix system.
	Decision: Deferred for clarification regarding method of manufacturing as the reference product is manufactured by OROS Push-Pull Technology while the submitted method of manufacturing for applied product is different.	
2365.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 50mg Tablets
	Diary No. Date of R& I & fee	Form-5D Dy.No 37929 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate……50mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D

	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 12,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	The firm has claimed In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). 06 month submit stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	
2366.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd, 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Safiget 100mg Tablets
	Diary No. Date of R& I & fee	Form-5D Dy.No 37928 dated 16-11-2018 Rs.50,000/- Dated 15-11-2018
	Composition	Each Film Coated Tablet Contains: Safinamide as Mesylate……100mg
	Pharmacological Group	antiparkinsonism
	Type of Form	Form 5D
	Finished Product Specification	Mfg Spec
	Pack Size & Demanded Price	30's, price Rs. 20,000/-
	Approval Status of Product in Reference Regulatory Authorities	Xadago (50mg & 100mg) film coated tablet by M/s US WORLDMEDS LLC, USFDA Approved
	Me-too Status	N/A
	GMP Status	Last inspection report dated 26/06/2018 acceptable level of GMP compliance.
	Remarks of the Evaluator-I	Stability data (Real time and Accelerated stability studies) as per guidelines/decision of 278th meeting Registration Board of 03 batches.
	Decision: Deferred for submission of stability data of 03 batches as per the guidelines/decision of 293rd meeting of Registration Board.	
2367.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 50mg/200mcg Tablets
	Diary No. Date of R& I & fee	Dy.No 38150 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…….……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 50 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Prostol Tablets by M/s Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore, Reg. No. 026839
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)

	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following; Each delayed release tablet contains: Diclofenac sodium…..50mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2368.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Diclotol 75mg/200mcg Tablets
	Diary No. Date of R& I & fee	Dy.No 38151 dated 19-11-2018 Rs.12,000/-
	Composition	Each Tablet Contains: Diclofenac Sodium (enteric coated core)…..……75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 75 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Arsofin Tablets by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Reg. no. 48013
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The composition of applied product is different from the reference product and is given in the following; Each delayed release tablet contains: Diclofenac sodium…..75mg Misoprostol…….200mcg While the composition of the reference product is; Each tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "delayed release tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2369.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Zipdone 40mg Capsule
	Diary No. Date of R& I & fee	Dy.No 38145 dated 19-11-2018 Rs.12,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….40mg

	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 40mg capsule of M/s Nabiqasim Industries (Reg.#055651)
	GMP Status	The GMP of the firm was satisfactory on the basis of inspected conducted on 11/03/2019. (Sections: Tablet general, Tablet Psychotropic, Capsule , General, Capsule Cephalosporin, Dry Powder Cepalosporin)
	Remarks of the Evaluator-I	The reference product contains Ziprasidone hydrochloride monohydtrate while the applied formulaiton contains Ziprasidone hydrochloride, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Ziprasidone Hydrochloride" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2370.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Applicant/Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Mol 1g/100ml Infusion (solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 37901 dated 16-11-2018 Rs.50,000/-
	Composition	Each 100ml Contains: Paracetamol…….1g
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paracetamol 10mg/ml Solution for Infusion (50ml vial, 100ml vial) by M/s Accord UK ltd, MHRA approved
	Me-too Status	Provas Infusion 10mg/ml by M/s Sami Pharma, Reg. No. 53223
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2371.	**Name and address of manufacturer / Applicant**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi

	Contract manufacturing	**Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ferolas 100mg/5ml Injection
	Diary No. Date of R& I & fee	Dy.No 37900 dated 16-11-2018 Rs.50,000/-
	Composition	Each 5ml (ampoule) Contains: Iron as Iron Sucrose……100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2372.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ton 8mg/4ml Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 37894 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each 4ml ampoule Contains: Ondansetron……8mg
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ondansetron 2 mg/ml (4mg/2ml & 8mg/4ml) Solution for Injection by M/s Hameln pharmaceuticals, MHRA Approved
	Me-too Status	Doston 8mg/4ml Injection by M/s Vision Pharmaceuticals, Kahuta Road, Islamabad. Reg. No. 081892
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials

		Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2373.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Lac 30mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37893 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Ampoule (1ml) Contains: Ketorolac Tromethamine……..30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Toradol Injection 30mg/ampoule of 1ml by M/s Atnahs Pharma, UK (MHRA Approved)
	Me-too Status	Tromit Injection by M/s harm (Reg.# 049958)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2374.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Bufin 10mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37891 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (1ml) Contains: Nalbuphine HCl……10mg
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved.
	Me-too Status	Nalburax Injection by M/s Mediceena Pharma (Pvt) Ltd, Reg. No. 28830
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available.

		Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2375.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Penzol 40mg/Vial Injection (Lyophilized powder for solution for injection)
	Diary No. Date of R& I & fee	Dy.No 37892 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Pantoprazole as Sodium ……..40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	**PROTONIX IV** 40mg Powder (freeze dried) for Solution for Injection by M/s Wyeth Pharms, USFDA Approved.
	Me-too Status	Zonpep Injection 40mg IV by M/s Aulton Pharmaceuticals, Reg. No.
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2376.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-D3 5mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 37895 dated 16-11-2018 Rs.50,000/-
	Composition	Each Ampoule (ml) Contains: Cholecalciferol……..5mg (Eq. to approx. 200,000IU)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5

	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too Status	G-Cal 5mg Injection by M/s Glitz Pharmaceuticals, Reg. No. 66362
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2377.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Zole 40mg/Vial IV Infusion (Lyophilized Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37896 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Omeprazole as Sodium…..…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2378.	**Name and address of manufacturer / Applicant**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi

	Contract manufacturing	**Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 1g Injection (Powder for solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 37899 dated 16-11-2018 Rs.50,000/- Dated 14-11-2018
	Composition	Each Vial Contains: Vancomycin as HCl…….1000mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	Vancocin Inection 1000mg of Eli Lilly Pakistan, Reg. No. 21081
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2379.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lasomycin 500mg Injection
	Diary No. Date of R& I & fee	Dy.No 37898 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Vancomycin as Hcl….500mg (powder for injection)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vancomycin Hydrochloride 500mg and 1g Powder for Concentrate for Infusion by M/s Hospira Uk , MHRA Approved.
	Me-too Status	VANCIN I.M / I.V INJECTION 500MG by M/s CENTURY PHARMACEUTICAL (PVT) LTD, Reg. No. 22673
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin

		Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2380.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Cycline 50mg Injection (Powder for solution)
	Diary No. Date of R& I & fee	Dy.No 37897 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Tigecycline……..50mg
	Pharmacological Group	Tetracycline derived antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tigecycline 50 mg lyophilized cake or powder for solution for infusion by M/s Mylan (MHRA Approved)
	Me-too Status	Tygacil Injection 50mg by M/s Wyeth (Reg#045642)
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2381.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Ronic 3mg/3ml Injection
	Diary No. Date of R& I & fee	Dy.No 37903 dated 16-11-2018 Rs.50,000/-
	Composition	Each 3ml Contains: Ibandronic Acid…….3mg
	Pharmacological Group	Bone resorption inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ibandronate sodium 3mg/3ml vial by M/s Sun Pharm, USFDA Approved.
	Me-too Status	Ibro injection 3mg/3ml by M/s Regal Pharmaceuticals (Reg#082004)

	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2382.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured By**: M/s Palpex Pharmaceuticals (Pvt) Ltd., St-1, Sector 38, Korangi Creek Industrial Park, Karachi **Manufactured for:** M/s Nicholas Pharmaceuticals, Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	N-Esom IV 40mg Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Dy.No 37902 dated 16-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Palpex Pharma**: GMP Certificate issued on 08/02/2019 on the basis of inspection conducted on 31/01/2019. Sterile Injectable Liquid vial section General Available. Sections: Tablet General Capsule General & Cephalosporin Dry Powder Suspension General and Cephalosporin Dry Powder Vial Injection Cephalosporin Sterile Injectable Liquid Ampoule Sterile injectable Liquid Vials Sterile Dry Powder Vials **Nicholas Pharma:** DML was issued w.e.f 29/08/2018 vide letter no. F.1-14/2014-Lic dated 29/08/2018.
	Remarks of the Evaluator-I	The applicant has 4 sections and no product is being manufactured on contract currently.
	Decision: Deferred for capacity assessment of M/s Nicholas Pharma.	
2383.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 4mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37921 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….4mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5

	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too Status	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2384.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Loxicam 8mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37926 dated 16-11-2018 Rs.20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam……..8mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too Status	Recam Tablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2385.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37922 dated 16-11-2018 Rs.20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008473 dated 24/01/2020.
	Decision: Deferred for; • **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
2386.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Parox-Q CR 12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37925 dated 16-11-2018 Rs.20,000/-

	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	Anti-depressants
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	The firm has revised the formulation from Film coated tablet to Eneric Film Coated Controlled Released Tablet and submitted Rs. 5000/- vide challan number 2008474 dated 24/01/2020.
	Decision: Deferred for; • **Submission of remaining fee of Rs. 15,000/- for revision of formulation as per the reference product.** • **Moreover, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
2387.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Uniterf Fort 250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 37923 dated 16-11-2018 Rs.20,000/-
	Composition	Each Tablet Contains: Terbinafine as HCL……250mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s NOVARTIS PHARMACEUTICALS UK LIMITED, MHRA Approved.
	Me-too Status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
2388.	Name and address of manufacturer / Applicant	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.
	Brand Name +Dosage Form + Strength	Dianil 2mg Capsule
	Diary No. Date of R& I & fee	Dy.No 37924 dated 16-11-2018 Rs.20,000/-
	Composition	Each Capsule Contains: Loperamide Hydrochloride…2mg
	Pharmacological Group	***Antidiarrheals***
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6×10, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loperamide Capsules 2 mg by M/s Galpharm Healthcare Limited, MHRA Approved.
	Me-too Status	LOPAMIDE 2mg CA by M/s Medicaids, Reg. No. 11240
	GMP Status	GMP status could not be confirmed
	Remarks of the Evaluator-I	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	

2389.	Name and address of manufacturer / Applicant	M/s Ciba Pharmaceutical private limitd, plot no. A-371, Nooriabad site industrial Area, Super highway Karachi.
	Brand Name +Dosage Form + Strength	LINO 500mg capsule
	Diary No. Date of R& I & fee	Dy.No.35276 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Lincomycin……..500mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2,6's×2, 5's×10, 10's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too Status	Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898
	GMP Status	According to the Last inspection report dated 07/02/2017, the firm is strictly following the GMP practice.
	Remarks of the Evaluator-I	The applied product is present in USP as well as BP. The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. Provide the proof of availability of Raman spectrometer if you want to claim USP specifications for the applied product. Provide evidence of approval of the applied product is Reference Regulatory Authorities approved by 275th meeting of Registration Board as the product is discontinued by USFDA and ANSM France.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2390.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16256 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82749
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2391.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan

		Manufactured By: M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16255 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…500gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82750
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2392.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Pime 1gm IV Injection
	Diary No. Date of R& I & fee	Dy.No 16566 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm with L-Arginine Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
2393.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore

	Brand Name +Dosage Form + Strength	J-Pime 500mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 16565 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Cefepime as HCl…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride with L-Arginine 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision: Deferred for consideration of the applications on its turn/queue.	
2394.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 250mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16247 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone (250mg & 1gm) powder for solution for injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 250mg IM by M/s Caliph pharmaceuticals (Pvt.) Ltd, Reg. no. 82556
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2395.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jizdime 250mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 16254 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019

	Composition	Each Vial Contains: Ceftazidime as Pentahydrate…250gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA MHRA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2396.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IM Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16250 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2397.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 500mg IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16249 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark pharmaceutical, Reg. No. 69751
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2398.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Cef 1g IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16251 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventek Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2399.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 100mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16257 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…100mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced

		Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2400.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 200mg/5ml Dry Powder Suspension
	Diary No. Date of R& I & fee	Dy.No 16258 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each 5ml (reconstituted) Contains: Cefixime as Trihydrate…200mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30 ml bottle, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2401.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cefiderm 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 16259 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Capsule Contains: Cefixime as Trihydrate….400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma:

		GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2402.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 1gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mg
	Pharmacological Group	
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2403.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16253 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…1gm Cefoperazone as Sodium…1gm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015 273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:**

		http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2404.	Name and address of manufacturer / Applicant	**Applicant:** M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan **Manufactured By:** M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	J-Sum 2gm IV Dry Powder Injection
	Diary No. Date of R& I & fee	Dy.No 16252 dated 07-03-2019 Rs.50,000/- Dated 06-03-2019
	Composition	Each Vial Contains: Sulbactam as Sodium…500mg Cefoperazone as Sodium…500mm
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Jinnah Pharma: The panel recommended renewal of DML, inspection date 03/05/2019. Aventeck Pharma: GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
	Remarks of the Evaluator-I	
	Decision: Deferred for consideration of the applications on its turn/queue.	
2405.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi
	Brand Name +Dosage Form + Strength	Diraximin 200mg Tab
	Diary No. Date of R& I & fee	Dy.No 266 dated 09/11/2016 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each Film Coated Tablet Contains: Rifaximin……200mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 200mg film-coated tablets, for oral use. **USFDA** approved
	Me-too Status	Nimixa 200mg Tablet film-coated. Reg. No. 70734

	GMP Status	The panel dated 04-10-2019 recommends for renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2406.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	NS+20K Infusion 100ml
	Diary No. Date of R& I & fee	Dy.No 71 dated 10/09/2013 Rs.50,000 Dated 10-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each ml contains: Sodium chloride……..9mg Potassium chloride…..150mg
	Pharmacological Group	Electrolytes
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml vial(as per SRO)
	Approval Status of Product in Reference Regulatory Authorities	Potassium Chloride 0.15% w/v & Sodium Chloride 0.9% w/v Solution for Infusion – BP by M/s Baxter healthcare, MHRA Approved. (strength is not same)
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	The applied product does not contain the same strength of potassium chloride as the product contains approved by reference regulatory authorities (RRAs). Provide evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revise the formulation along with the applicable fee. evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for; • **Evidence of approval of the same formulation in same strength and filled volume in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2407.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Acbenzo 4% w/w Cream
	Diary No. Date of R& I & fee	Dy.No 1399 dated 13/01/2017 Rs.20,000 Dated 05-01-2017 **Duplicate file** The file is received from R-I Section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 100g cream contains: Benzoyl Peroxide….4g
	Pharmacological Group	Anti infective
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Brevoxyl 4% Cream by M/s GSK consumer healthcare, MHRA Approved.
	Me-too Status	Prayzid Cream 4% cream by M/s Pray Pharma, Reg. No. 72415

	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2408.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colonclean Syrup
	Diary No. Date of R& I & fee	Dy.No 69 dated 10/09/2013 Rs.50,000 Dated 04-09-2013 **Duplicate file** The file is received from R-I Section section vide letter No.F.6-10/2013-Reg-II dated 20/02/2020.
	Composition	Each 5ml contains: Sodium potassium monobasic….2.4g Potassium dibasic…….0.9g
	Pharmacological Group	Purgative
	Type of Form	Form-5D
	Finished Product Specification	In House
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 28-06-2018, Good level of GMP
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for; • **Evidence of approval of the same formulation in RRAs as specified by Registration Board in 275th meeting or otherwise revision of the formulation along with the applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2409.	Name and address of manufacturer / Applicant	**Manufacturer:** M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore **Applicant:** M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd , Lahore
	Brand Name +Dosage Form + Strength	Cewel Dry suspension 100mg/5ml
	Diary No. Date of R& I & fee	Dy.No 5800 dated 05/07/2010 Rs.8,000 Dated 03-07-2010 Differential fee 42,000/- dated 22/01/2015 **Duplicate file** The application is received from R-II section vide letter no. F.1-11/2019-Reg-II dated 24/12/2019.
	Composition	Each 5ml reconstituted suspension contains: Cefixime Trihydrate equivalent to Cefixime…100mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	Harmann Pharma: **Decision of 272st Meeting of CLB:**

		I- Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections. a- Sterile Section-I (General Injection) b- Sterile Section-III (Hormonal Injection) II- Regularize the layout plan of Hormonal Section, as per recommendations of the panel in the reort dated 13-06-2019 & 08-10-2019. Synchro Pharma: Inspection report dated 30/06/2020. "it was observed that firm had rectified most of the shortcomings and for remaining shortcomings fir was advised to submit CAPA within stipulated time and re-inspection will be conducted accordingly".
	Remarks of the Evaluator.	Copy of agreement is attached The applicant has stated that there are no products being manufactured on contract. M/s Harmann Pharma has 7 approved sections.
	Decision: Deferred for confirmation of required manufacturing facility "Dry Powder suspension cephalosporin section" for applied formulation.	
2410.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nystanil oral solution 100,000 units/ml
	Diary No. Date of R& I & fee	Dy.No 9908 dated 25/07/2017 Rs.20,000 **Duplicate dossier** The application is received from R-I section vide letter no. F.1-2/2019-Reg-I dated 01/01/2020.
	Composition	Each ml contains: Nystatin……100,000 units
	Pharmacological Group	antimycotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nystatin Oral Suspension BP by M/s Sandoz ltd, MHRA approved.
	Me-too Status	Nystrin Suspension 100,000/- per ml by M/s Harmann Pharma, Reg. No. 28119
	GMP Status	09-10-2018 Routine GMP Inspection "overall GMP compliance level is rated as good." Liquid syrup section is available.
	Remarks of the Evaluator.	• The applied product is Oral Solution while the approved product is reference country is Oral Suspension, provide the evidence of approval in reference regulatory authorities as approved by Registration Board in 275th meeting or otherwise submit revised formulation as per reference product along with the submission of applicable fee. • The firm has revised formulation the formulation from Oral Solution to Oral Suspension as per the reference product and submitted fee (Rs. 5,000/- challan number 1976772 dated 30/07/2020 + Rs. 15,000/- challan number 2034651 dated 09/09/2020).
	Decision: Approved with the following details; **Brand name:** **Nystanil oral suspension 100,000 units/ml** **Label Claim:**	

	Each ml contains: **Nystatin……100,000 units** **Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.**	
2411.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra Injection 500mg/5ml
	Diary No. Date of R& I & fee	Dy.No 14122 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each 5ml contains: Levetiracetam…500mg
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 325/- per ampoule
	Approval Status of Product in Reference Regulatory Authorities	KEPPRA 500mg/5ml Injection of USFDA approved
	Me-too Status	Lumark Injection M/s Searle Pak
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Injectable section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2412.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Levra 100mg/ml Oral solution
	Diary No. Date of R& I & fee	Dy.No 14123 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file** The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each ml contains: Levetiracetam…100mg
	Pharmacological Group	antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs 432/- per 60ml, Rs. 720/- per 120ml
	Approval Status of Product in Reference Regulatory Authorities	LEVETIRACETAM (Levetiracetam100mg/ml) solution; oral By M/s TARO. USFDA Approved.
	Me-too Status	Levotam Oral solution 100mg/ml By M/s Platinum, Karachi. (Reg.# 070837)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Oral liquid section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2413.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Oxepin Capsules 3/25mg
	Diary No. Date of R& I & fee	Dy.No 14124 dated 06-09-2017 Rs.20,000 Dated 06-09-2017 **Duplicate file**

		The application is received from R-II section vide letter no.F.1-11/2019-Reg-II dated 24th December, 2019.
	Composition	Each capsule contains: Olanzapine……..3mg Fluoxetine as HCl…….25mg
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 20/- per capsule
	Approval Status of Product in Reference Regulatory Authorities	Symbyax 3mg/25 mg Capsules by Ms/ Eli Lilly, USA (USFDA approved).
	Me-too Status	Olanco Capsules by Genome Pharma. (Reg. # 079388)
	GMP Status	GMP inspection dated 19-10-2017 satisfactory level of compliance. Capsule section available
	Remarks of the Evaluator.	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2414.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore. **Manufacturer:** M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Esomark 40mg Infusion Lyophilized powder for infusion
	Diary No. Date of R& I & fee	Dy.No 3083 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Esomeprazole as Sodium…..400mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.
	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2415.	Name and address of manufacturer / Applicant	**Applicant:** M/s Sapient Pharma, 123/S Quaid e Azam Industrial Estate Kot Lakhpat , Lahore. **Manufacturer:** M/s English Pharmaceutiacl Industries Link kattar bund road, Thokar Niaz Baig, Multan road Lahore.
	Brand Name +Dosage Form + Strength	Biomep 40mg Infusion

		Lyophilized powder for solution
	Diary No. Date of R& I & fee	Dy.No 3084 dated 15-05-2013 Rs.150,000 Dated 15-05-2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 14/02/2020.
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	English Pharma: Certificate of GMP Issued on 16-01-2018. Sapient Pharma: GMP certificate issued on 22/04/2020 on the basis of inspection conducted on 18/11/2019.
	Remarks of the Evaluator-I	Copy of contact agreement is submitted, 5 sections of M/s Sapient Pharmaceutical Industries are approved. M/s Sapient Pharmaceutical Industries have 13 product being manufactured on contract.
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2416.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Phlocin Injection
	Diary No. Date of R& I & fee	Dy.No 485 dated 21-03-2014 Rs.20,000 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II.
	Composition	Each 4ml ampoule contains: Phloroglucinol hydrate…….40mg Trimethylphloroglucinol…..0.04mg
	Pharmacological Group	Antispasmodic.
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too Status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP Status	GMP certificate issued on 10/12/2018 on the basis of inspection conducted on 08/11/2018. Liquid injectable section available
	Remarks of the Evaluator-I	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2417.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Florlina Plus powder
	Diary No. Date of R& I & fee	Dy.No 12 dated 01-07-2015 Rs.20,000 Dated 30-06-2015

		Duplicate file
	Composition	Each 100g contains: Neomycin Sulphate……15gm Florfenicol……..10gm Oxytetracycline Hcl……..30gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	100gm, 200gm 500gm, 1kg, price decontrolled
	Me-too Status	NEOXFLOR ORAL POWDER (150mg, 100mg 300mm per gram) by M/s Baariq Pharma, Reg. No. 088638
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Deferred for updated status of GMP from QA & LT division.	
2418.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Enflox-c plus liquid
	Diary No. Date of R& I & fee	Dy. No 13 dated 01-07-2015 Rs.20,000 Dated 30-06-2015 **Duplicate file**
	Composition	Each 100ml contains: Enrofloxacin……..…10mg Cloistin sulphate…….100mg Amantadine HCl…..…300gm
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished Product Specification	Inhouse
	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Evidence of GMP is required.
	Remarks of the Evaluator.	
	Decision: Deferred for following: **Updated status of GMP from QA & LT division.** **Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name & name of firm.**	
2419.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Colate powder for solution for injection
	Diary No. Date of R& I & fee	Dy.No 39066 dated 29-11-2018 Rs.20,000 Dated 27-11-2018 (Duplicate file)
	Composition	Each vial contains; Colistimethate sodium…..……1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Date of inspection 10/04/2019, acceptable level of cGMP compliance
	Remarks of the Evaluator-I	
	Decision: Approved. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	

2420.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Janumet tablet
	Diary No. Date of R& I & fee	Dy.No 28 dated 01-07-2014 Rs.20,000 Dated 01-07-2014 **Duplicate file**
	Composition	Each tablet contains: Sitagliptin……..50mg Metformin HCl……..500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 1,500/- per pack of 2×7's
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	The firm has submitted the correct composition as per the reference product given in the following without submission of any fee. Each film coated tablet contains: Sitagliptin as phosphate monohydrate……..50mg Metformin HCl…….500mg
	Remarks of the Evaluator.	
	Decision: Deferred for submission of requisite fee for revision of formulation as per reference product.	
2421.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Relspasm Injection 4mg/2ml
	Diary No. Date of R& I & fee	Dy.No 749 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(02/06/2011)+12,000(14/01/2015) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each ml contains: Thiocolchicooside……2mg
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis (ANSM France)
	Me-too Status	Myolax 2mg Injection (4mg/2ml ampoule) by M/s Saffron, Reg. no. 60355
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019. Liquid injectable section is available.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2422.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Derams Injection 500mg IV

		Powder for solution
	Diary No. Date of R& I & fee	Dy.No 748 (10/02/2020) Dated of submission: 04/06/2011 Fee: 8,000(03/06/2011)+12,000(16/12/2014) **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 12/02/2020. Dated 09-01-2015
	Composition	Each vial contains: Thiopental sodium…500mg (as a mixture of Thiopental sodium and sodium carbonate)
	Pharmacological Group	Genera anesthetic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Thiopental Sodium 500mg Powder for Solution for Injection by M/s Kyova kirin ltd, MHRA Approved.
	Me-too Status	M-Pentone 500mg Injection by M/s Mediate, Reg. No. 61946
	GMP Status	GMP certificate issued on 05/09/2019 on the basis of inspection conducted on 08/08/2019. Dry powder injectable section is available.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification of method of manufacturing of the applied product whether via lyophilization or dry powder filling alongwith reference / innovator's product manufacturing method.	
2423.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunate injection 250mg Powder for injection
	Diary No. Date of R& I & fee	Dy.No 166 dated 03-11-2016 Rs.20,000 Dated 02-11-2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone as sodium succinate……250mg
	Pharmacological Group	Glucocorticoid-Minerolcorticoid
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Hydrocortisone as sodium succinate Injection-USFDA
	Me-too Status	Solu-cortef by Pfizer Pharma
	GMP Status	Date of inspection 11-02-2019, good level of GMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of required manufacturing facility/section approval from Licensing division.	
2424.	Name and address of manufacturer / Applicant	M/s Zakfas pharmaceutical pvt Ltd. 12-Km, bosan raod, multan.
	Brand Name +Dosage Form + Strength	Gen-One topical spray
	Diary No. Date of R& I & fee	y.No 546 dated 09-06-2016 Rs.50,000 Dated 09-06-2016
	Composition	Each ml contains: Gentamicin as sulphate…….0.57mg Betamethasone as valerate……0.284mg
	Pharmacological Group	Antibiotic/corticosteroid
	Type of Form	Form-5D
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Me-too Status	Could not be confirmed

	GMP Status	
	Remarks of the Evaluator.	Section approval letter. GMP inspection report International availability. Stability required.
	Decision: Deferred for following; • **Required manufacturing facility/section approval from Licensing Division.** • **Latest GMP inspection report.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2425.	Name and address of manufacturer / Applicant	M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Exelor 50mg tablet
	Diary No. Date of R& I & fee	Dy.No 10146 dated 26-07-2017 Rs.20,000 Dated 24-07-2017
	Composition	Each film coat tablet contains: Vildagliptin……..50mg
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GALVUS (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pvt Ltd. TGA approved
	Me-too Status	V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908)
	GMP Status	Inspection date, 27/12/2018, the firm is working in compliance to GMP standards.
	Remarks of the Evaluator-I	The firm has revised the formulation from Film Coated to Uncoated Tablet with submission of Rs. 5000/- challan no. 1938304 dated 08/12/2019 as per the reference product given in the following; Each Tablet contains: Vildagliptin……..50mg
	Decision: Approved with innovator's specifications	
2426.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Azocin 250mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 (slip no. **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……250mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 150/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269

	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2427.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Azocin 500mg tablet
	Diary No. Date of R& I & fee	Dy.No dated 24/05/2011 Rs.8000/- Dated 24/05/2011 Rs. 20,000/- 20/02/2013 **Duplicate file** The file is received from R-II section vide letter No.F.1-11/2019-Reg-II dated 01/06/2020.
	Composition	Each tablet contains: Azithromycin as dihydrate……500mg
	Pharmacological Group	Antiobiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 275/- per 6's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269
	GMP Status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
2428.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Global Pharmaceuticals, Plot No. 204-205, Industrial Triangle, Kahuta road, Islamabad. **Manufacturer:** M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Glonate Injection 250mg
	Diary No. Date of R& I & fee	Dy.No 166 dated 03/11/2016 Rs.20,000/- dated 02/11/2016 + Rs. 30,000/- 10/11/2016 **Duplicate file**
	Composition	Each vial contains: Hydrocortisone sodium succinate…….250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Global Pharma: Inspection date 26/12/2018, panel recommended renewal of DML.

		Vision Pharma: Inspection date 11/02/2019, the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	Clarification is required since the product approved in reference country contains "Hydrocortisone as sodium succinate 250" while the label claim of the applied product is "Hydrocortisone sodium succinate 250mg". Form 5 is submitted by the manufacturer while it should be submitted by the applicant. Detail of number of products being manufactured for M/s Global Pharmaceuticals is required. Provide number of approved sections of M/s Global Pharmaceuticals.
	Decision: Deferred for submission of the followings; • **Evidence of approval of applied formulation containing "Hydrocortisone sodium succinate 250mg" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Form 5 is submitted by the manufacturer while it should be submitted by the applicant.** • **Detail of number of products being manufactured for M/s Global Pharmaceuticals is required.** • **Provide number of approved sections of M/s Global Pharmaceuticals.**	
2429.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……1000mgs
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/1000 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53404
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2430.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sitavin 50mg/1000mg Tablets
	Diary No. Date of R& I & fee	Dy. No. 40987 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50 Metformin HCL ……500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	

	Decision: Approved with innovator's specifications.	
2431.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Demant 5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40986 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…5mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Torrent 5mg Film-coated Tablets by M/s Torrent Pharma (UK) Ltd, MHRA Approved.
	Me-too Status	Afdol 5mg Tablets by M/s AGP (R # 047166)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2432.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Demant 10mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41017 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…10mg
	Pharmacological Group	antiparkinson
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Memantine Accord (5mg, 10mg, 15mg, 20mg) film-coated tablets by M/s Accord, MHRA Approved.
	Me-too Status	Afdol 10mg Tablets by M/s AGP (R # 044429)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2433.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 250mg
	Diary No. Date of R& I & fee	Dy. No. 41005 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….250mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote 250mg Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 250mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024464)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

2434.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Rox tablet 500mg
	Diary No. Date of R& I & fee	Dy. No. 41006 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Valproic acid (as Divalproex Sodium)….500mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Depakote (250mg, 500mg) Gastro-resistant tablet by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too Status	Epinil 500mg Tablets by M/s Platinum Pharmaceuticals (Pvt) Ltd (Reg#024465)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2435.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 20mg
	Diary No. Date of R& I & fee	Dy. No. 40997 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……20mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 20mg tablet by M/s Getz Pharma, Reg. No. 33430
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovatpr's specifications.	
2436.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sezgol Tablet 40mg
	Diary No. Date of R& I & fee	Dy. No. 40998 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium (20mg, 40mg) gastro-resistant tablets by M/s AstraZeneca UK Limited,MHRA Approved.
	Me-too Status	Nexum 40mg tablet by M/s Getz Pharma, Reg. No. 33431
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2437.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals,

		Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Omefit 40mg Capsules
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Omeprazole enteric coated pellets…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Losec Capsule (20mg, 40mg) by M/s Astra Zaneca (MHRA Approved)
	Me-too Status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	Source= Vision Pharma,
	Decision: Approved.	
2438.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 25mg
	Diary No. Date of R& I & fee	Dy. No. 40989 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..25mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 25mg Tablet by M/s Apotex Technologies USFDA Approved)
	Me-too Status	Paroxin CR Tablets 25mg by M/s Shrooq pharmaceuticals (Reg#060470).
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2439.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino CR tablet 12.5mg
	Diary No. Date of R& I & fee	Dy. No. 40990 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Enteric, film coated Controlled Release Tablet Contains: Paroxetine as HCl……..12.5mg
	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR 12.5mg Tablet of M/s Apotex Technologies (USFDAApproved)
	Me-too Status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	

	Decision: Approved.	
2440.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 10mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41004 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amlodipine and Olmesartan Medoxomil 10/20mg film coated tablet by M/s Torrent USFDA Approved.
	Me-too Status	Omsana-AM 10/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58559
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2441.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	A-O tablet 5mg/20mg
	Diary No. Date of R& I & fee	Dy. No. 41003 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 5/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58557
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2442.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metlipsy 800mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41000 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Piracetam 800mg film-coated tablet by M/s USB Pharma, MHRA approved
	Me-too Status	Nootropil Tablet 800mg by M/s GSK Reg. No. 82277

	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2443.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mydin 10mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41024 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each tablet contains: Loratadine……..10mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Roletra 10 mg Tablets by M/s Ranbaxy (UK) Limited. MHRA approved
	Me-too Status	Senergy OD 10mg tablet by M/s Highnoon (Reg.#017672)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
2444.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 20mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.…20mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 20mg tablet by M/s ' Highnoon Laboratories, Reg. no. 48371
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2445.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rovas 40mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41007 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.…40mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Aurora Tablets 40mg by M/s Ferozsons Laboratories, Reg. no. 54747

	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2446.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Relaxer tablet 4mg
	Diary No. Date of R& I & fee	Dy. No. 41019 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each uncoated tablet contains: Thiocolchicoside ……4mg
	Pharmacological Group	Anti Parkinson, neuralgia
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	THIOCOLCHICOSIDE EG 4 mg, scored tablet. **ANSM France** approved
	Me-too Status	Myolax Tablets 4mg by M/s Reko Pharma Reg. No. 74170
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
2447.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Konaz cream 2% w/w
	Diary No. Date of R& I & fee	Dy. No. 41023 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each gram contains: Ketoconazole… 20mg (2% w/w)
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Daktarin Gold 2% Cream by M/s McNeil Products Limited, MHRA Approved.
	Me-too Status	Bizrole Cream 2 % by M/s Searle IV Solutions (Pvt.) Ltd, Reg. No. 78620
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
2448.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Binaf Cream 1% w/w
	Diary No. Date of R& I & fee	Dy. No. 41021 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Gram of cream contains: Terbinafine as HCl ……..10mg (1%)
	Pharmacological Group	Anti fungal
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Terbinafine HCl 1% cream by M/s Taro, USFDA Approved

	Me-too Status	Terbisan caream 1% by M/s Elko organization (PvT) ltd. Reg # 27076
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today. Ointment/cream/gel/lotion (non-steroidal) section is approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
2449.	**Name and address of manufacturer / Applicant**	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metacid Oral Suspension
	Diary No. Date of R& I & fee	Dy. No. 41030 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each 5ml contains: Aluminium hydroxide…….215mg Magnesium hydroxide…….80mg Simethicone…….25mg
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be verified
	Me-too Status	Simecrol Suspension by M/s Hicon Pharmaceuticals (Reg.#041458)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

b. Deferred Cases (Local manufacturing) Human

2450.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi. (8 sections)
	Brand Name +Dosage Form + Strength	MAXI Eye Drops (Opthalmic Solution)
	Diary No. Date of R& I & fee	Dy.No.35273 dated 12/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Moxifloxacin as HCl…….5mg
	Pharmacological Group	Anti-infective/Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MOXIVIG 0.5%w/v eye drops, solution by M/s Novartis Pharmaceuticals UK Limited, MHRA Approved.
	Me-too Status	Ocumox-D Eye Drops by M/s Remington Pharmaceutical Industries, Reg No. 67888
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution and submitted Rs. 5000/- vide Callan number 1909480 dated 29/11/2019. The applicant has 08 sections.

		The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035976 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Moxifloxacin as HCl…….5mg (Opthalmic solution) **Decision: Approved.**	
2451.	**deleted**	
2452.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	KATS sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35269 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Ketorolac Trimethamine……5mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	MFG
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketorolac trometamol 0.5% w/v eye drops, solution by M/s Brown & Burk UK Ltd,MHRA Approved.
	Me-too Status	Ketro 0.5% Eye Drops by Ms/ Vega Pharmaceuticals (Pvt) Ltd, Reg No. 54030
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has claimed In-House manufacturing specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The firm has revised the formulation of the applied product from ophthalmic suspension to ophthalmic solution and submitted Rs. 5000/- vide challan number 1909484 dated 29/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035977 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Ketorolac Tromethamine……5mg (Opthalmic solution) **Decision: Approved with innovator's specifications.**	
2453.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.

	Brand Name +Dosage Form + Strength	PATLERG sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35270 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml contains: Olopatadine as HCl……..1mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Olopatadine 1 mg/ml Eye drops, Solution by M/s Brown & Burk UK Ltd, MHRA Approved.
	Me-too Status	Zolopat 0.5% eye drops by Ms/ Remington Pharmaceutical Industries**,** Reg. No. 065991
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909483 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution". **Submission by the firm:** The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035978 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..1mg (Opthalmic solution) **Decision: Approved.**	
2454.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Manufactured by:** M/s Medicaids Pakistan (pvt) ltd. Plot # 10, Sector 27, Korangi Industrial Area Karachi. **Manufactured for (Applicant):** M/s Inventor Pharma. Plot No..K-196, SITE (SHW) Phase II, Karachi.
	Brand Name +Dosage Form + Strength	PATLERG FORTE Sterile ophthalmic solution
	Diary No. Date of R& I & fee	Dy.No.35271 dated 24/10/2018 PKR 50,000/-
	Composition	Each ml of suspension contains: Olopatadine as HCl……..2mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	OLOPATADINE HYDROCHLORIDE 0.2% opthalmic solution by M/s CIPLA, USFDA Approved.
	Me-too Status	Plop Forte Ophthalmic solution 2mg/ml by M/s Genix Pharma, Reg. No. 73680
	GMP Status	GMP certificate issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator.	The firm has revised the formulation from ophthalmic suspension to ophthalmic solution along with the submission of Rs. 5000/- vide challan number 1909482 dated 29th/11/2019. The firm has submitted that they are not having any registration on the basis of contract manufacturing.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 45000/- for revision of formulation from "Opthalmic suspension" to Opthalmic solution".	

	Submission by the firm: The firm has submitted differential fee of Rs. 45,000/- vide challan number 2035979 dated 02/09/2020 for revision of formulation from Opthalmic suspension to Opthalmic solution as per the reference product. The correct label claim is given in the following; Each ml contains: Olopatadine as HCl……..2mg (Opthalmic solution) **Decision: Approved.**	
2455.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Omezole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40951 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial vontains: Omeprazole as Sodium…40mg (Lyophilized powder)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2456.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Lorno 8mg for Injection IV/IM
	Diary No. Date of R& I & fee	Dy. No. 43539 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial contains: Lornoxicam……8mg (Lyopilized powder)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too Status	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for following: e. Confirmation whether application is by lyophilization process or powder filling. f. Registration status of M/s Biolab for same formulation. **Submission of the firm:** a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2457.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Esozole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40952 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg (Lyophilized powder of Esomeprazole sodium)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided.	

	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2458.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awablock 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole……40mg"
	Diary No. Date of R& I & fee	Dy. No 11728 dated 30-03-2018 Rs.50,000/- Dated 29-03-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi, (Reg#050651)
	GMP status	Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision of 295th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. The firm has applied for Esomeprazole 40mg while reference product contains Esomeprazole as sodium 40mg. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2459.	Name and address of manufacturer / Applicant	Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad Manufactured by Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	EPI 40mg Injection
	Composition	Each vial contain: Esomeprazole (as Sodium).....40mg
	Diary No. Date of R& I & fee	Dy. No. 5781 Date:29-08-2016 Rs. 50,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Nexium I.V. 40mg of (MHRA approved)
	Me-too status (with strength and dosage form)	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance
	Previous Remarks of the Evaluator [IV]	Contract agreement attached

		Number of already registred contract manufactured products: Nil
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products **(M-282)**
	Evaluation by PEC	Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision of 295th meeting: Registration Board deferred the case for confirmation of dry powder vial filling facility. **Submission of the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2460.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winlor 8mg Injection
	Composition	Each Vial Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 1153 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved
	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for following:	

	• confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise. • DML status of M/s Alen **Submission by the firm:** a. The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic (Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. b. M/s Biolabs Pvt ltd does not have the registration of the applied formulation. c. The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for following: **Confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.** **Confirmation of DML status of M/s Alen Pharmaceuticals pvt. Ltd, Risalpur.**	
2461.	**Name and address of manufacturer / Applicant**	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	BIMEP 40MG INJECTION IV
	Composition	Each vial contains: Omeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19491, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2462.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore **contract manufactured by** M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	NULOC 40MG INJECTION IV
	Composition	Each vial contains: Esomeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19492, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house

	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Nexium IV 40mg powder for solution for injection of AstraZeneca, UK (MHRA)
	Me-too status	Somezol Injection of Bosch, Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad (M-291).
	Evaluation by PEC	The firm has submitted that now M/s. Bio-Lab Pvt. Ltd has enhanced its capacity.
	Previous decision (M-293)	Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Firm's response	The product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. M/s Biolabs has been granted the relevant section for lyophilization vide letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012.
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2463.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winrose Injection 100mg/5ml
	Composition	Each ampoule contains: Iron sucrose…100mg
	Diary No. Date of R & I & fee	Dy. No. 1152 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• Revise the label claim and salt from in line with the reference product along with submission of applicable fee. • The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	

2464.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zolid 600mg/300ml Infusion
	Composition	Each Vial Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 1151 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	D Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
2465.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Locrim 400mg Infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 1154; 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP

		as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	Decision of 295th meeting: Deferred for DML status of M/s Alen. **Submission by the firm:** The firm has submitted receiving of submission of application for Renewal of DML on 18th Sep, 2019. Renewal of DML is due from 16/09/2019.	
	Decision: Deferred for confirmation of DML status of M/s Alen Pharmaceuticals pvt ltd, Risalpur.	
2466.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Esofil 40mg IV Injection (Lyophilized Powder for Solution)
	Diary No. Date of R& I & fee	Form-5 Dy.No 38082 dated 19-11-2018 Rs.50,000/- Dated 16-11-2018
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic(Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
2467.	**Name and address of manufacturer / Applicant** **Contract manufacturing**	**Applicant:** M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad. **Manufactured By:** M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Noctis 40mg IV Injection (Lyophilized powder for solution)
	Diary No. Date of R& I & fee	Dy.No 38081 dated 19-11-2018 Rs.50,000/-
	Composition	Each Vial Contains: Omeprazole as Sodium……40mg
	Pharmacological Group	PPI
		Form 5
	Finished Product Specification	Mfg specs

	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	M/s Nabi Qasim was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate. M/s Saffron Pharma, Last GMP inspection conducted on 08-10-2019, Good level of GMP.
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). The applicant has submitted that they are not having any manufacturing on contract basis from any firm. Currently the firm have 08 sections.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The applied product would be manufactured by way of Lyophilization at approved facility of M/s Nabi Qasim Industries (pvt) ltd.. Section approval letter no. F.2-20/85 Lic (Vol-III)(M-227th) dated 20th June, 2011 for Lyophilized vials (General) is provided. **Decision: Approved with innovator's specifications.**	
2468.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-Penta injection IV
	Diary No. Date of R& I & fee	Dy. NO 633, 20-3-15, 50,000/-
	Composition	Each vial contains:- Pantoprazole lyophilized…….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Protonix by Wyeth (USFDA)
	Me-too status	Neege by Sami pharma
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration

		of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2469.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Albepra injection
	Diary No. Date of R& I & fee	Dy. NO 636, 20-3-15, 50,000/-
	Composition	Each vial contains:- Omeprazole sodium equivalent to omeprazole….40mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	1's As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of Sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided.	

	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2470.	**Name and address of manufacturer / Applicant**	M/s Albro Pharmaceuticals,340/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore applied for contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Alb-EZO injection
	Diary No. Date of R& I & fee	Dy. NO 634, 20-3-15, 50,000/-
	Composition	Each vial contains:- Esomeprazole (as Sodium)……..40mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished Product Specification	As per innovator
	Pack size & Demanded Price	1's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole of Consilient pharma (MHRA)
	Me-too status	Brince of ACE
	GMP status	Last inspection conducted on 29.08.2017 for additional section
	Remarks of the Evaluator.	• This plant possesses 3 sections (tablet, Capsule, Oral liquid) The firm has got registration of 16 products, on contract manufacturing as per information provided by the applicant
	Decision of previous meeting of Registration Board	Registration Board deferred the case for clarification of number of products which are being manufactured on contract manufacturing since the firm has got registration of 16 products on contract manufacturing. (**M-277)**
	Evaluation by PEC	Firm has 3 approved sections and already got registration of 16 products, but after 277th meeting the firm has submitted a letter for de registration of 8 already registered products on contract manufacturing by Shrooq pharma and synchro pharma. The Registration Board in its 291st meeting acceded the request of the firm and decided to cancel the registration of those 8 products. Now the firm has submitted request against 6 deferred cases.
	Decision of 293rd meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. **Submission by the firm:** The firm has submitted that the product would be manufactured by way of Lyophilization at approved facility of Bio-labs (pvt) ltd. Section approval letter no. F.1-12/89-Lic(Vol-II) dated 23rd July, 2012 for Lyophilized vials (General) is provided. **Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.**	
2471.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Clida Gel 1%
	Diary No. Date of R& I & fee	Dy.No 43888 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Clindamycin Phospate eq to Clindamycin…1% 10mg

	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	RESIDERM 1%w/w GEL by M/s Crawford Healthcare Limited (MHRA Approved)
	Me-too Status	Clindacin Gel 1%w/w by M/s Sante (Reg#067485)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	
2472.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sisul Cream, 1%
	Diary No. Date of R& I & fee	Dy.No 43886 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Silver Sulfadiazine…1% (w/w)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Silvadene Cream 1% of USFDA approved
	Me-too Status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision of 295th meeting: Deferred for confirmation of approval of relevant/required manufacturing facility. Submission by the firm: The firm has submitted letter No.F.1-8/2001-Lic dated 8th May, 2018 issued by Secretary, Central Licensing Board whereby the firm has granted Topical Preparation Section. **Decision: Approved.**	
2473.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jusidic Eye Drops
	Diary No. Date of R& I & fee	Dy.No 43887 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gm contains: Fusidic acid…1%
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucithalmic 1%w/w viscous eye drops, MHRA Approved
	Me-too Status	Fusitek Eye Drops 1% by M/s Invotek Pharma, Reg. No. 26957
	GMP Status	Same as stated above Ear/Eye Drops (General/Steroidal) section approved.
	Remarks of the Evaluator.	The firm has revised the formulation from 1% w/v to 1% w/w without submission of fee.
	Decision of 293rd meeting: Deferred for submission of applicable fee for revision of formulation.	

	Submission by the firm: The firm has submitted the fee Rs. 5,000/- vide challan number 1932506 dated 12/08/2020. **Decision: Approved.**	
2474.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hisone 250mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42385 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Hydrocortisone sodium Succinate eq to Hydrocortisone…250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision of 295th meeting: Deferred for confirmation of section in M/s Rotex Pharma Pvt Ltd . Submission by the firm: The applicant has submitted Sterile Dry Powder Vial (Steroid) Section approval letter No. F.1-53/2003-Lic(Vol-I) dated 4th Dec, 2018 issued by Secretary Licensing Board. **Decision: Aprproved.**	
2475.	Name and address of Applicant	M/s Excel Healthcare Laboratories Pvt Ltd. House. D#122, Block 4 Federal B Area Karachi, Pakistan.
	Name and address of manufacturer	M/s Pharma vision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey
	Marketing authorization holder	M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey
	Exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 35530 Dated 25-10-2018
	Fee including differential fee	Rs. 50,000/- Dated 25-10-2018
	Brand Name +Dosage Form + Strength	Gembag 100mg/2ml Solution for IM Injection
	Composition	Each ampoule contains: Iron III hydroxide polymaltose complex….333.33mg (Eq. to 100mg elemental iron)
	Finished Product Specification	Firm claim In-House specification
	Pharmacological Group	Parenteral iron preparation
	Shelf life	24 Months
	Pack size & Demanded Price	2ml glass ampoule & As per SRO
	International availability	FERRUM H iron 100mg/2mL (as polymaltose) injection ampoule (TGA Australia)
	Me-too status	Reg No. 041029by M/s Schazo Pharma Lab.
	Stability studies	Firm has submitted long term (24 months) at 30+2°C, 65+5%RH & accelerated (06 months) stability data at 40+ 2°C, 75+ 5% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 2018/1000) issued on 07-03-2018 by Republic of Turkey Ministry of Health Turkish

		Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Pharmavision San. Ve Tic. A.S. Davutpasa Cad. No: 145 Topkapi/Istanbul- Turkey. This certificate is valid until 17-03-2020. • Original product specific Sole agency agreement dated 23rd March 2018 of importer M/s Excel Healthcare Laboratories Pvt Ltd with Product License Holder M/s WORLD MEDICINE ILAC SAN. VE TIC. A.S. Gunesli, Bagcilar/ Istanbul, Turkey.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of differential fee i.e. 50,000/- since the applied formulation is already registered by DRAP. Evaluation by PEC: The firm has submitted differential fee Rs. 50,000/- vide challan number 2001025 dated 13/08/2020. **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Firm will provide valid CoPP for further processing of case.**	
2476.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Laderfex-D Tablet 60/12 0
	Composition	Each tablet contains:- Fexofendine HCl…….60mg Pseudoephedrine HCl……..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10954 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D Tab of Sanofi Aventis, USFDA
	Me-too status	Fenadrin D Tablet of Noa Hemis (Reg#042352)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
2477.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Hirafen-Plus Tablet 200mg/30mg
	Composition	Each film coated tablet contains:- Ibuprofen…….200mg Pseudoephedrine HCl……..30mg
	Diary No. Date of R& I & fee	Dy. No 10824 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	NSAID/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC

	Approval status of product in Reference Regulatory Authorities.	Advil Cold and Sinus of Pfizer, USFDA
	Me-too status	Rovinac Tablets of Rock Pharma (Reg# 064206)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. **Decision: Approved with innovator's sepcifications.**	
2478.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Slorit-D Tablet 2.5/120
	Composition	Each tablet contains:- Desloratadine……2.5mg Pseudoephedrine Sulfate…..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10953 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067246)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
2479.	Name and address of manufacturer / Applicant	M/s Hiranis pharmaceuticals (Pvt.) Ltd. plot No.E-145 to E-149, North Western Industrial Zone, port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Slorit-D Tablet 5/240
	Composition	Each tablet contains:- Desloratadine……5mg Pseudoephedrine Sulfate…..240mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10955 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067247)
	GMP status	As recorded for above application

	Remarks of the Evaluator	
	Decision of 289th meeting: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division. Evaluation by PEC: The firm has submitted letter No. F.1-33/2009-Lic dated 07/02/2014 whereby the firm has been granted for Tablet General Section. As the applied product is bilayer and it is evident from the provided inspection report dated 13/02/2019 conducted for Renewal of DML that the firm has Double Layer Tablet Compression Machine in "Psychotropic Tablet Section". While Inspection conducted for grant of DML dated 23/09/2013 shows that the Bilayer tablet machine is available in Tablet (General) Section as well. **Decision: Approved.**	
2480.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals, 19 Km G.T. road, Kalashah Kaku, Lahore.
	Brand Name +Dosage Form + Strength	COLIMETH Dry powder for Injection
	Diary No. Date of R& I & fee	Dy.No. 35528 dated 25/10/2018 PKR 20,000/-
	Composition	Each vial contains; Colistimethate Sodium……1MIU (eq. to 80mg)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's
	Approval Status of Product in Reference Regulatory Authorities	Promixin, 1 million International Units (IU), Powder for Solution for Infusion, which is approximately equivalent to 80 mg of colistimethate sodium by M/s Zambon S.p.A., MHRA Approved.
	Me-too Status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP Status	Last inspection report dated 20/09/2017 concludes the overall condition of the firm as satisfactory.
	Remarks of the Evaluator.	
	Decision of 289th meeting: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Submission by the firm: The firm has submitted that lyophilized raw material will be imported and filled in General Powder Filling section. The firm has been granted Dry Powder Injection (General) Section vide section approval letter No. F.1-63/84-Lic (Vol-III-A) dated 3rd October, 2019. **Decision: Approved.**	
2481.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR-300 Tablets
	Diary No. Date of R& I & fee	Dy.No 41447 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Extended Release Tablet Contains: Quetiapine as Fumarate…300mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm:	

	The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 300mg Tablet of M/s Hilton Pharma , Reg No. 76087. **Decision: Approved.**	
2482.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR 150 Tablets
	Diary No. Date of R& I & fee	Dy.No 41448 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…150mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 295th meeting: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Submission by the firm: The firm has provided following me too reference which has been verified from the available data base**;** Qusel XR 150mg Tablet of M/s Hilton Pharma , Reg No. 067501. **Decision: Approved.**	
2483.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Ceftax 250mg Injection
	Composition	Each vial contains: Cefotaxime (as cefotaxime sodium)……. 250mg
	Diary No. Date of R& I & fee	Dy. No. 10774 dated 05/03/2019 R. 20,000/- dated 05/03/2019
	Pharmacological Group	Antiobiotic
	Type of Form	Form 5
	Finished Product Specification	B.P
	Pack size & Demanded Price	1's, as per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Cefon injection 250mg (vial) of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision pf 291st meeting: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by CIMA Spain and the reference provided by the firm has been verified and given in the following; Caefotaxima Normon 250mg powder and solvent for injectable IV EFG (Status: Marketed). Each vial contains: Cefotaxime as sodium…… 250mg	

	The website was accessed on 29/06/2020. https://cima.aemps.es/cima/publico/lista.html **Decision: Approved.**	
2484.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	CLOBAM Tablet 10mg
	Composition	Each tablet contains: Clobazam……..10mg
	Diary No. Date of R & I & Fee	Dy No.12236 dated 06-03-2019 ; Rs.20,000 06/03/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	B.P Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Onfi tablet (10mg, 20mg) by M/s Lundbecl Pharms LLC, USFDA Approved
	Me - too Status	Frisium tablet 10mg Reg No 2692
	G. M. P. Status	Inspection report dated 22/02/2019 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for scientific justification of overage present in the applied formulation.	
	Evluation by PEC: The firm has submitted revised formulation along with the master formula omitting the overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2485.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	DINOP – E2 Tablet 3mg
	Composition	Each tablet contains: Dinoprostone…….. 3mg
	Diary No. Date of R & I & Fee	Dy. No.6511 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Prostaglandin Analog
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Prostin E2 vaginal tablet by M/s Pfizer MHRA Approved
	Me - too Status	Prostin E-2 by Pfizer vaginal tablets (Reg. No. 009821)
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The firm has applied for **oral tablet** while the product approved in reference authority is **Vaginal Tablet**.
	Decision of 293rd meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Evaluation by PEC: The firm has stated that it was a typographical error and Oral Tablet was written instead of Vaginal Tablet. The evidence of approval in reference authority and me-too status have already been verified	

	as Vaginal tablet. Following is the correct label claim submitted by the firm. The firm has no tsubmitted any fee. Each vaginal tablet contains: Dinoprostone…….. 3mg **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2486.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	TENIL Tablet 6mg
	Composition	Each Tablet Contains: Bromazepam……6mg
	Diary No. Date of R & I & Fee	Dy. No.6506 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Apo-bromazepam tablet (1.5mg, 3mg, 6mg) by M/s Apotex Inc. Health Canada Approved
	Me - too Status	Yazd 6mg Tablet By M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65693
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation without overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2487.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.25mg
	Composition	Each Tablet Contains: Alprazolam……. 0.25mg
	Diary No. Date of R & I & Fee	Dy No.6501 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.25mg by M/s Pfizer, MHRA Approved
	Me - too Status	Lydia 0.25mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65697
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage.	

	Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.	
2488.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 0.5mg
	Composition	Each Tablet Contains: Alprazolam……. 0.5mg
	Diary No. Date of R & I & Fee	Dy No.6502 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.50mg by M/s Pfizer, MHRA Approved
	Me - too Status	Lydia 0.50mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65705
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2489.	Name & Address of Manufacturer Applicant	M/S Legacy Pharmaceuticals (Pvt) Ltd111-A, Industrial Estate Hayatabad Peshawar - 25000 K. P. K Pakistan
	Brand Name + Dosage Form + Strength	XINIL Tablet 1 mg
	Composition	Each Tablet Contains: Alprazolam……. 1 mg
	Diary No. Date of R & I & Fee	Dy No.6503 dated 14-02-2019 ; Rs.20,000 14/02/2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 1.0mg by M/s Pharmacia and Upjohns, USFDA Approved
	Me - too Status	Lydia 1.0mg Tablets by M/s. Wilshire Laboratories (Pvt) Ltd; Reg No. 65699
	G. M. P. Status	Inspection report dated 29/08/2018 confirms satisfactory level of cGMP compliance.
	Remarks of Evaluator	The proposed formulation contains overage with no scientific justification.
	Decision of 293rd meeting: Deferred for the following scientific justification of overage present in the applied formulation.	
	Evaluation by PEC: The firm has submitted revised formulation of the product omitting overage. **Decision: Deferred for confirmation of requisite manufacturing facility / Section for manufacturing of the applied product.**	
2490.	**Name and address of manufacturer / Applicant**	**M/s Ciba Pharmaceutical private limitd, plot no.** A-371, Nooriabad site industrial Area, Super highway Karachi.

	Brand Name +Dosage Form + Strength	VOXY 100mg capsule
	Diary No. Date of R& I & fee	Dy.No.35275 dated 24/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Doxycycline as hyclate…….100mg
	Pharmacological Group	tetracycline
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's×2, 5's×6, 5's×10, 5's×20, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Doxycycline 100mg Capsules by M/s Kent Pharmaceuticals Ltd, MHRA Approved.
	Me-too Status	Medox Capsule 100mg by M/s Maxitech, Reg. No. 84781
	GMP Status	GMP certificate has been issued on 20/08/2019 based on inspection conducted on 07/08/2019.
	Remarks of the Evaluator.	The firm has revised the formulation from doxycycline monohydrate to Doxycycline as hyclate as per the composition of the reference product **without submission of Fee.**
	Decision of 293rd meeting: Deferred for submission of fee (Rs. 20,000/-) for revising the formulation from doxycycline monohydrate to Doxycycline as hyclate as per the composition of the reference product.	
	Evaluation by PEC: The firm has submitted Rs. 20,000/- vide challan no. 0768949 dated 11/03/2020 for revision of formulation as per the reference product. The following is the correct label claim of the applied product. Each capsule contains: Doxycycline as hyclate…….100mg **Decision: Approved.**	
2491.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Midaz 7.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 38054 dated 19-11-2018 Rs.20,000/-
	Composition	Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg
	Pharmacological Group	Sedative/Hypnotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's price Rs. 200/-, 20's price Rs. 250/-
	Approval Status of Product in Reference Regulatory Authorities	Dormicum (7.5mg & 15mg) film coated Tablets by M/s CHEPLAPHARM Arzneimittel GmbH, Netherlands Approved.
	Me-too Status	Dorminic Tablets 7.5mg tablet by M/s Dosaco Laboratories, Reg No. 24295
	GMP Status	The firm was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). Alternate brand name: Mezolam Saf-mif • The firm has revised the formulation of applied product from **Midazolam as Hydrochloride** to **Midazolam as Maleate** and submitted fee Rs. 5000/- vide challan number 0828860 dated 12/12/2019.
	Decision of 293rd meeting: Deferred for submission of differential fee of Rs. 15000/- for revision of formulation.	

	Evaluation by PEC: The firm has submitted remaining fee of Rs. 15,000/- vide challan number 0828873 dated 17/02/2020 for revision of formulation as per the reference product. Following is the correct label claim of the product. Each Film coated Tablet Contains: Midazolam as Maleate……7.5mg **Decision: Approved with innovator's specifications.**	
2492.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	TARADOL tablet 37.5mg/325mg
	Diary No. Date of R& I & fee	Dy.No. 35264 dated 24/10/2018 PKR 20,000/-
	Composition	Each Film Coated tablet contains: Tramadol hydrochloride…….37.5mg Paracetamol…….325mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as recommended by PRC
	Approval Status of Product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP Status	Last inspection report dated 26/10/2018, the firm is not found working as required under the law rule.
	Remarks of the Evaluator.	
	Decision of 293rd meeting**:** Registration Board referred the case to QA & LT Division to conduct GMP inspection of firm on priority.	
	Evaluation by PEC: The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved.**	
2493.	**Name and address of manufacturer / Applicant**	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Diary No. Date of R& I & fee	Dy.No 35106 dated 23-10-2018 Rs.20,000/- Dated 22-10-2018
	Brand Name +Dosage Form + Strength	Velanef 800mg Tablets
	Composition	Each Film Coated Tablet Contains: Sevelamer HCL…800mg
	Pharmacological Group	Phosphate Binder
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renagel 800mg Tablet by M/s Genzyme Corporation, (USFDA approved)
	Me-too status	Renavel 800mg Tablet by M/s AllianzeMed Pharmaceuticals (Reg No:075510)
	GMP status	26-10-2018. The firm is not found working as required under the law/rule
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for updated GMP status of the firm from QA&LT Division. **Evaluation by PEC:** The firm has submitted last inspection report dated 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. (letter NO. F.3-2/2007-FID-I(ISB) dated 19/12/2019). **Decision: Approved with innovator's specifications.**	
2494.	Duplication	
2495.	**Name and address of manufacturer / Applicant**	AJM Pharma, Plot No. 44, sector No. 27 korangi Inustrial Area Karachi
	Brand Name +Dosage Form + Strength	Asclop tablet 75mg/75mg

	Diary No. Date of R& I & fee	Dy. No. 1315 dated 03/05/2017 Re. 20,000/-
	Composition	Each film coated tablet contains: Clopidogrel as bisulfate…. 75mg Acetyl salicylic acid……75mg
	Pharmacological Group	ADP induced platelet aggregation inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 220/- per pack of 10's
	Approval Status of Product in Reference Regulatory Authorities	CoPlavix Tablet Clopidogrel (as hydrogen sulfate) and aspirin by M/s sanofi-aventis, (TGA Approved)
	Me-too Status	Clodril Plus Tablet M/s Macter International, Reg. No. 55982
	GMP Status	Same as for the previous case
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP). Alternate brand names: Asplat Clopiclot
	Decision of 293rd meeting: Deferred for clarification of the dosage of the Innovator product, whether bilayer tablet or otherwise. Evaluation by PEC: The firm has submitted the applied product is not bilayered while it is immediate release film coated tablet. The statement has not been verified from EMA assessment report. The product approved in EMA is bilayered. **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee along with the proof of availability of bilayer tabletting machine.**	
2496.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.2
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….20mg
	Composition	Dy. No. 7989 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ezetimibe and Atrovastatin calcium (USFDA)
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section.	

	Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
2497.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62 industrial estate, kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.4
	Diary No. Date of R& I & fee	Each film coated tablet contains: Ezetimibe……..10mg Atrovastatin….40mg
	Composition	Dy. No. 7990 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form -5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ezetimibe and Atrovastatin calcium (USFDA)
	Me-too Status	
	GMP Status	DML of M/s CCL pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "the firm was found to be satisfactory level of GMP compliance".
	Remarks of the Evaluator.	The applied product was already registered in the name of the applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision of 291st meeting: Deferred for confirmation of status of previous registration from RRR section. Current Status: RRR section was asked for current status of renewal of the applied products vide letter no. F.9-1/2019-PEC dated 2nd march, 2020. The RRR section has stated that "as per available record, the renewal submission of the products overleaf is not available". The case is hereby place before the Board. **Decision: Approved with innovator's specifications**.	
2498.	Name and address of manufacturer/Applicant	M/s Pharmix Laboratories (Pvt.) Ltd., 21-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Prozol Capsule 30mg
	Composition	Each capsule contains: Enteric coated pellets eq. to Lansoprazole….30mg (Source of Pellet M/s Murli Krishna Pharma Pvt. Ltd. D-98, Ranjangaon, Taluka-Shirur, Pune 412209 Maharashtra state, India)
	Diary No. Date of R& I & fee	Dy. No. 32736 dated 02-10-2018, Rs. 15,000/- dated 15-10-2009, and Rs. 85000/- dated 22-09-2016
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs.425/Pack of 14's
	Reference Regulatory Authorities status	Lansoprazole 30 mg gastro-resistant capsules (UK)
	Me-too status	Arcozol Capsules 30mg of M/s Pakistan Pharmaceutical Products (Pvt) Ltd, Karachi

	GMP status	GMP inspection by inspectors dated 31-05-2018 & 01-06-2018 shows the acceptable level of compliance of GMP.
	Remarks of the Evaluator	Provided stability studies of Lansoprazole pellets 8.5%w/w at 30±2^{0}C, 65%±5% RH of 12 months and at 25±2^{0}C, 60%±5% RH of 48 months
	Decision of 293rd meeting: Deferred for submission of stability data of pellets through shelf life as per Zone IVA. Submission by the firm**:** The firm has submitted long term stability study data of 03 batches for 36 months period according to the conditions of zone IV-A. However, accelerated stability data is not submitted. **Decision: Deferred for submission of Accelerated Stability data of 03 batches of pellets.**	
2499.	Name and address of manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories, Plot # 9A, St#N-5, National Industrial Zone, (RCCI) Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Soulpride 50mg Tablet
	Diary No. Date of R& I & fee	Diary No, Date of R & I & fee Dy. No. 22438 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Composition	Each tablet contains: Levosulpride……..50mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Inovator's specification
	Pack Size & Demanded Price	20's & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	
	Me-too Status	Sulprex Tablets 50mg of M/s Global Pharmaceuticals GMP Status DML by way of formulation No. 000871 dated 13-09-2017.
	GMP Status	Could not be confirmed
	Remarks of the Evaluator.	
	Decision of 292nd meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Evaluation by PEC: The applied product is approved by AIFA Italy. LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved. Each tablet contains: Levosulpride……..50mg GMP status of the firm could not be confirmed. **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**	
2500.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, Faisalabad Road Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 60mg Injection
	Composition	Each vial contains: Artesunate ……60mg
	Diary No. Date of R& I & fee	Dy. No 28674 Dated 27-08-2018, Rs. 50,000/- dated 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Gen-M 60mg Injection of M/s Genix Pharma (Pvt) Ltd.

	GMP status	M/s Nabiqasim Industries Pvt. Ltd: DML by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP M/s Surge Laboratories Pvt. Ltd: cGMP inspection dated 05-05-2019 shows good level of cGMP compliance of the firm.
	Remarks of the Evaluator	
	Decision of 292nd meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Now the firm has submitted the evidence of WHO recommended formulation which is access dated 06th December 2019 http://archives.who.int/eml/expcom/expcom15/applications/formulations/artesunate.pdf Decision of 293rd meeting: Deferred for evidence of approval of requisite manufacturing facility from licensing division. Submission by the firm: The applicant has submitted that M/s Surge Laboratories was granted Additional section of Dry Powder Injectable (General) vide letter No. F.1-18/95-Lic(Vol-III) dated 7th July, 2020. The copy of letter is attached with the submission. **Decision: Approved with innovator's specifications.**	

Case No. 2. Registration Applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases (Local manufacturing) Veterinary

2501.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-KM chakbeli road, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	MAXIFLOR 30% Oral Liquid
	Diary No. Date of R& I & fee	Dy.No. 35265 dated 24/10/2018 PKR 20,000/-
	Composition	Each 100ml contains: Florfenicol……30% (w/v)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack Size & Demanded Price	Plastic bottle of 100ml, 500ml, 1000ml, price decontrolled
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 18/08/2017 concludes the overall GMP compliance level as good.
	Remarks of the Evaluator.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

b. Deferred cases (local manufacturing) Veterinary

2502.	Name and address of Applicant/ Manufacturer	M/s Farm Aid Group Plot # 3/2, phase I & II, Hattar Industrial Estate, Haripur
	DML	DML by way of formulation dated 25-10-2015.
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 16299 Dated 03-05-2018
	Fee including differential fee	Rs. 20,000/- Dated 02-05-2018

	Brand Name +Dosage Form + Strength	MOXY CS POWDER
	Composition	Each 1000gram contains: Amoxicillin Trihydrate……150gm Colistin sulphate……25gm
	Finished Product Specification	Firm claim innovator's specification
	Pharmacological Group	Antibiotic
	Demanded Price	Decontrolled
	Pack size	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg
	Me-too status	Moxicoli water soluble powder of m/s zumars pharma (pvt) ltd. Karachi.
	GMP status	GMP inspection dated 03-10-2018 **Conclusion:** During the inspection, some suggestions were given for improvement and certain shortcomings were also identified. The Firm's management looked committed in rectifying the shortcomings and assured to do so in the shortest possible time. Therefore, keeping in view the environmental, manufacturing and quality control facilities provided, discussions made with the technical personnel, the documentations presented and reviewed, the raw materials consumed in manufacturing of the registered products and commitment of the firm's management in rectifying the shortcomings, the firm M/s Farm Aid Group Haripur is considered to be maintaining satisfactory level of the cGMP and found to be fulfilling GMP requirements
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for evidence of approval of requisite maujfacturing facility (penicillin) from licensing division. **Submission by the firm:** The firm has submitted approval letter No.F.3-9/91-Lic(Vol-I) dated 21st June, 2017 for Dry Powder Section (Vet) section. **Decision: Deferred for confirmation of required manufacturing facility "Dry Powder penicillin (Veterinary)" section.**	

Case No. 3: **Registration Applications of Newly Granted DML or New Section (Veterinary)**

a. New Section:

Vet New Section

M/s Medi-Excel Pharmaceutical, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad was granted additional sections vide letter no. F.1-2/2001-Lic (Vol-I) dated 29/09/2019. The firm has applied for following products against relevant sections as under.

GENERAL INJECTABLE SECTION (VET) NEW One product/molecule was approved in 294th meeting of Registration Board in General Injectable Section (Vet). Further 9 molecules and 29 products are remaining.		
NO OF MOLECULES		**NO PRODUCTS**
9		**31**
2503.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20823 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	50ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2504.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 10 Injection
	Composition	"Each ml Injection contains: Ivermectin……10 mg"
	Diary No. Date of R& I & fee	Dy. No 20824 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Actimec Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 034595)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2505.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20825 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2506.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Iverexcel 20 Injection
	Composition	"Each ml Injection contains: Ivermectin……20 mg"
	Diary No. Date of R& I & fee	Dy. No 20826 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml /Decontrolled
	Me-too status (with strength and dosage form)	Selmec Injection (10ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that

		was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2507.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20827 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2508.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 7.5 Injection
	Composition	"Each ml contains: Meloxicam…….7.5mg"
	Diary No. Date of R& I & fee	Dy. No 20828 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Camilox Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 071089)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2509.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20829 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
	Name and address of manufacturer /	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282

2510.	Applicant	Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 10 Injection
	Composition	"Each ml contains: Meloxicam…….10mg"
	Diary No. Date of R& I & fee	Dy. No 20830 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Meloxi-10 Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 049643)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2511.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains: Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20831 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2512.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Melowin 20 Injection
	Composition	"Each ml contains: Meloxicam…….20mg"
	Diary No. Date of R& I & fee	Dy. No 20832 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Melocam-20 Injection (10ml, 20ml, 30ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 057007)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2513.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"

	Diary No. Date of R& I & fee	Dy. No 20833 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2514.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flunixel 50 Injection
	Composition	"Each ml contains: Flunixin Meglumine……..50mg"
	Diary No. Date of R& I & fee	Dy. No 20834 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Loxin Injection (10ml, 20ml, 50ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 035098)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2515.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20835 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2516.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20836 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled

	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2517.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Ketoexel 100 Injection
	Composition	"Each ml contains: Ketoprofen……..100mg"
	Diary No. Date of R& I & fee	Dy. No 20837 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Ketoject Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 043141)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2518.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20838 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2519.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20839 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2520.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nitroxl 34 Injection
	Composition	"Each ml contains: Nitroxynil…….340 mg"
	Diary No. Date of R& I & fee	Dy. No 20840 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Troxy 34% Injection (10ml, 20ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 034597)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2521.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20841 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection 100ml vial of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2522.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20842 dated 20-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.

	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2523.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 12 Injection
	Composition	"Each ml contains: Ivermectin……..20 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20843 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec DS Injection **100ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 101524)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2524.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20844 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2525.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20845 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that

		was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2526.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	MEKSOL 11 Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Clorsulon……..100 mg "
	Diary No. Date of R& I & fee	Dy. No 20846 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Plus Injection (10ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 033251)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved.	
2527.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20847 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec Forte Injection **50ml vial** of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . 102087)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2528.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20848 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5

	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec forte injection 50ml vial by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2529.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Mekvita Injection
	Composition	"Each ml contains: Ivermectin……..10 mg Vitamin A……..25000IU Vitamin D……..3750IU Vitamin E ……..25mg
	Diary No. Date of R& I & fee	Dy. No 20849 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic and Vitamin
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10 ml/Decontrolled
	Me-too status (with strength and dosage form)	Actimec forte injection **50ml vial** by M/s Selmore, Reg. No. 102087
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The filled volume of already registered product is different from the applied product.
	Decision: Deferred for evidence of applied formulation/drug in the applied filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2530.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone……. 50 mg"
	Diary No. Date of R& I & fee	Dy. No 20853 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2531.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Buparxel Injection
	Composition	"Each ml contains: Buparvaquone…….50 mg"
	Diary No. Date of R& I & fee	Dy. No 20854 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiprotozoal

	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Parvon Injection (10ml, 20ml, 40ml and 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 034580)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	The applied filled volume of 50ml is not approved while other filled volumes that 10ml, 20ml, 40ml and 100ml are approved.
	Decision: The Board approved the case with innovator's specifications with a filled volume of 50mL as already approved filled volumes range from 10mL to 100mL.	
2532.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	" Each ml contains: Closantel……..50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20857 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	100 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specfiications.	
2533.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Closxel Injection
	Composition	"Each ml contains: Closantel……..50mg Levamisole HCl…...100mg
	Diary No. Date of R& I & fee	Dy. No 20858 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	50 ml/Decontrolled
	Me-too status (with strength and dosage form)	Levamiclosan Injection (10ml, 25ml, 50ml, 100ml vial) of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# . . 062075)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
BOLUS SECTION (VET) NEW		
NO OF MOLECULES		**NO PRODUCTS**
10		13
2534.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 152 Bolus
	Composition	"Each bolus contains: Albendazole……..152 mg"

	Diary No. Date of R& I & fee	Dy. No 20810 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-S Bolus 152mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043139)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2535.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road, Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 600 Bolus
	Composition	" Each bolus contains Albendazole……600 mg"
	Diary No. Date of R& I & fee	Dy. No 20811 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	5's, 10's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-C Bolus 600mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043138)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2536.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Albexcel 2500 Bolus
	Composition	" Each bolus contains Albendazole……2500 mg"
	Diary No. Date of R& I & fee	Dy. No 20812 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Albensel-2500 Bolus 2500mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 043137)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2537.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Flumexcel 350 Bolus
	Composition	" Each bolus contains Flumequine……..350 mg"
	Diary No. Date of R& I & fee	Dy. No 20813 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled

	Me-too status (with strength and dosage form)	Flumequine Bolus 350mg of M/s Zakfas Pharmaceuticals Pvt Ltd, (Reg.# 074754)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2538.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Fenexcel 750 Bolus
	Composition	"Each bolus contains: Fenbandazole…….750 mg"
	Diary No. Date of R& I & fee	Dy. No 20814 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Fenbal-Bolus 750mg of M/s Wimits Pharmaceuticals Pvt Ltd, (Reg.# 078319)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2539.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Nicloexcel 1250 Bolus
	Composition	"Each bolus contains: Niclosamide……1250 Mg"
	Diary No. Date of R& I & fee	Dy. No 20815 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Niclover Bolus 1250mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046572)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2540.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Santexcel 500 Bolus
	Composition	"Each Bolus contains: Closantel…….500 Mg"
	Diary No. Date of R& I & fee	Dy. No 20816 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Flukinil Bolus 500mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 046571)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2541.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Trileva 99 Bolus
	Composition	"Each Bolus contains: Triclabendazole……900 mg Levamisole HCl……90 mg"
	Diary No. Date of R& I & fee	Dy. No 20817 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribazole Plus Bolus 900mg/90mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 074039)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2542.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Trissen 1000 Bolus
	Composition	"Each Bolus contains: Trimethoprim……200 mg Sulphadiazine ……..1000 mg"
	Diary No. Date of R& I & fee	Dy. No 20818 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Tribactral Bolus 200mg/1000mg of M/s Selmore Pharmaceuticals, (Reg.# 029617)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2543.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Suldimexcel 2.5 Bolus
	Composition	"Each Bolus contains: Sulphadimidine Sodium…….2.5 Gm"
	Diary No. Date of R& I & fee	Dy. No 20819 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Sulfapri Bolus 2.5gm of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 063683)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
	Name and address of manufacturer /	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282

2544.	Applicant	Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermexcel Bolus
	Composition	"Each Bolus contains: Levamisole HCl……1125 mg Oxyclozanide……2250 mg"
	Diary No. Date of R& I & fee	Dy. No 20820 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Zanisol Bolus1125mg/2250mg of M/s Prix Pharmaceuticals, (Reg.# 044979)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2545.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 400 bolus
	Composition	"Each bolus contains: Levamisole HCl……..400 mg"
	Diary No. Date of R& I & fee	Dy. No 20821 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	LEVA 400 BOLUS of M/s Intervac, (Reg.# 072651)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2546.	Name and address of manufacturer / Applicant	"M/s Mediexcel Pharmaceuticals Islamabad. Plot # 282 Industrial Triangle, Kahuta Road Humak, Islamabad 45700, Pakistan"
	Brand Name +Dosage Form + Strength	Vermout 1125 Bolus
	Composition	"Each bolus contains: Levamisole HCl……..1125 mg"
	Diary No. Date of R& I & fee	Dy. No 20822 dated 21-08-2020 Rs. 20,000/- 20-08-2020
	Pharmacological Group	Antiparasitic/ Dewormer
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 50's and 100's / Decontrolled
	Me-too status (with strength and dosage form)	Levasel Bolus 1125mg of M/s Selmore Pharmaceuticals Pvt Ltd, (Reg.# 029618)
	GMP status	Firm has submitted copy of GMP certificate (Sr.No.0709) that was issued on 08-10-2019 & Copy of renewed DML No. 000519 on Dated: 02-11-2019.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

Case No. 4: **Registration Applications of Import Cases.**

a. New Cases Human Import

2547.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.

	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No: 8137 Dated : 25/02/2019
	Fee including differential fee	Rs: 50,000 Dated : 25/02/2019
	Brand Name +Dosage Form + Strength	Amomax 3g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…….2g Salbactum sodium equivalent to Salbactum……..1g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 608/- per vial (1's)
	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	N/A
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052203 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.
	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China authorized M/s biocare.
	Decision: Approved as per policy for inspection of manufacturer abroad.	
2548.	Name and address of Applicant	M/s Biocare Pharmaceutical 807 Shadman-1, Lahore, Pakistan.
	Detail of Drug Sale License	License to sell drugs as Distributor Address: Biocare Pharmaceuticals, 807 shadman-1, District Lahore. Validity: 17/04/2020 The firm has submitted receipt for renewal of DSL dated 15/07/2020.
	Product License Holder & Manufacturer	Manufacturer & MAH: M/s Reyoung Pharmaceutical Co., Ltd., No.1 Ruiyamg Road, Yiyuan County, Shandong Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 8136 Dated : 25/02/2019
	Fee including differential fee	Rs : 100,000 Dated : 25/02/2019

	Brand Name +Dosage Form + Strength	Amomax 1.5g for injection Powder for injection
	Composition	Each vial contains: Ampicillin sodium equivalent to Ampicillin…. 1g Salbactum sodium equivalent to Salbactum….. 0.5g
	Finished Product Specification	USP
	Pharmacological Group	Penicillin/beta lactamase inhibitor
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 407/- per vial (1's)
	International availability	Unasyn for injection (2g/1g, 1g/500mg) by M/s Pfizer USFDA approved.
	Me-too status	To be confirmed
	Stability studies	36 months real time stability and 06 months accelerated stability study data as per zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018052202 **Certified by:** Yiyuan Food and Drug Administration **Date of issuance:** 28/05/2018 **Free sale:** Yes **GMP status:** conformance to WHO-GMP **GMP certificate:** Certificate no. SD20180716 valid till 12/06/2023 issued by Shandong Food and Drug Administration.
	Remarks of the Evaluator.	Copy of Distributorship & & Agency Agreement Contract is submitted where REyoung Pharmaceuticsal Co., Ltd., No.1 Ruiyang Road, Yiyuan Couunty Shandong PRC, 256100 China
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2549.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	Drug license by way of whole sale Address: Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2, 2nd floor West Land trade centre plot no. C-5, Block 7/8, KCHSU, Shaheed e Millat road Karachi. Validity: 09/10/2020
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1674 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 40mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)……40mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 27/- per Cap
	International availability	Losec Capsule 40mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.

	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Sole agency agreement is required. Free sale certificate is issued by authority not recognized by WHO.
	Decision: Deferred for submission of sole agency agreement/letter of authorization and confirmation of zone stability under stability studies were conducted..	
2550.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (private) Limited, Office no. D-2, 2nd floor, west land trade centre, plot # c-5, Block 7/8 KCHSU, Shaheed e Millat Road Karachi.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Product License Holder & Manufacturer	**Manufacturer & MAH:** Reyoung Pharmaceutical Co., Ltd. Workshop 312 from Reyoung Pharamceutical Co., Ltd., Ruiyang Road, Yiyuan county, Shandong province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1673 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Dopra 20mg capsule
	Composition	Each capsule contains: Omeprazole (extended release pellets)..……20mg
	Finished Product Specification	USP
	Pharmacological Group	PPI
	Shelf life	3 years
	Pack size & Demanded Price	Rs. 20/- per Cap
	International availability	Losec Capsule 20mg by M/s Astra Zaneca (MHRA Approved)
	Me-too status	Meprascot Capsules 20mg by M/s Scotmann Pharmaceuticals (Reg#028238)
	Stability studies	6 months accelerated and 36 months long term data as per zone IV-A provided by the firm.
	Detail of certificates attached	**Original legalized Free Sale Certificate** **Certificate No**: 2018-0908 **Certified by:** Yiyuan County Food & Drug Administration **Date of issuance:** 08/09/2018 (valid for 5 years) 20mg and 40mg omeprazole capsules are freely sold in the exporting country. **GMP certificate:** SD201880652, valid till 29/01/2023, issued by Shandong food and drug administration
	Remarks of the Evaluator.	Original sole agency agreement is required. Free sale certificate is issued by authority not recongnized by WHO.
	Decision: Deferred for submission Sole Agency Agreement/letter of authorization.	
2551.	Name and address of Applicant	M/s Aster Life Sciences, 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore.

		Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1215 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 500mg IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..500mg
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 500 mg powder for solution for injection or infusion by M/s Milpharm Limited, MHRA Approved.
	Me-too status	Mopen 500mg Injection by M/s Hilton pharma, Reg. No. 36429.
	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1738 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018 **Free sale:** Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied fromulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to deferred the case for clarification of salt form.	
2552.	Name and address of Applicant	M/s Aster Life Sciences , 32 Babar block, New Garden Town, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Aster Life Sciences 32-Baber block, New Garden Town, District Lahore. Validity: 29/11/2019 The firm has submitted receipt for renewal of DSL 25/11/2019.
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Jeil Pharmaceutical Co., Ltd., 7 Cheongganggachang-ro

		Baegam-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1216 Dated 10/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 10/01/2019
	Brand Name +Dosage Form + Strength	Newropenem Injection 1g IV Powder for injection
	Composition	Each vial contains: Meropenem as trihydrate…..1g
	Finished Product Specification	USP
	Pharmacological Group	Carbapenem
	Shelf life	3 years
	Pack size & Demanded Price	As per SRO
	International availability	Meropenem 1g powder for solution for injection or infusion by M/s Hikma, MHRA Approved.
	Me-too status	Mopen 1g Injection by M/s Hilton pharma, Reg. No. 36427.
	Stability studies	24 months long term and 06 month accelerated stability data according to the conditions of zone IV-A.
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 2018-D1-1736 **Certified by:** Gyeongin Regional Food and Drug Administration **Date of issuance:** 23/07/2018 **Free sale:** Yes **GMP status:** The manufacturer conforms to WHO and PIC/s GMP as per CoPP **GMP certificate:** Expired (validity May 17, 2020), issued by Ministry of Food and Drug Safety, Korea.
	Remarks of the Evaluator.	Justification is required since 2% overage is added in the formulation as per submitted dossier. As per submitted CoPP, the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate" as well as USP describes the assay of the product in terms of base only (Meropenem as trihydrate), clarify.
	Decision: As the CoPP describes the composition of the applied formulation the formulation contains "Meropenem Hydrate" while the product approved in reference regulatory authorities contains "Meropenem As Trihydrate", therefore the Board decided to defer the case for clarification of salt form.	
2553.	Name and address of Applicant	M/s Scilife Pharma (pvt) Limited, Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Product License Holder & Manufacturer	**Manufacturer & MAH:** M/s Laboratorio Eczane Pharma S.A, Laprida 43, Avellaneda, Buenos Aires, Argentina.
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 6951 Dated 19/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 19/02/2019
	Brand Name +Dosage Form + Strength	Xelotab 500mg tablet
	Composition	Each film coated tablet contains:

		Capecitabine……..500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	24 months
	Pack size & Demanded Price	2083.3/- per 10's, 6250/- per 30's, 12500/- per 60's, 25000/- per 120's
	International availability	Capecitabine 500 mg film-coated tablets by M/s Glenmark Pharmaceuticals Europe Limited, MHRA Approved.
	Me-too status	MERICAP 500MG film coated tablet by M/s Merixil pharma, Reg. No. 81801
	Stability studies	24 months data for real time and 6 months of accelerated data.
	Detail of certificates attached	**Original CoPP** **Certificate No**: 191912 **Certified by:** National Institute of drugs **Date of issuance:** 28/08/2018 **Free sale:** Yes **GMP status:** The facilities and operations conform to WHO-GMP as per CoPP.
	Remarks of the Evaluator.	Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature* *that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16598/2020* *Tariff: 6.12.3* *Amount: ARS 300/-* *Date: 01/20/2020* *Observations*
	Decision: Deferred for review of stability data as per Zone IVA	
2554.	Name and address of Applicant	M/s Zam Zam Pharmaceutical, Suit No. 205,206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi, Pakistan.
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Zam Zam Pharmaceutical , Suit no. 16 Beaumont Road Karachi. Validity: 15/02/2022
	Product License Holder & Manufacturer	**Manufacturer (**Primary and secondary packaging**):** M/s Haupt Pharma amareg GmbH Donaustaufer Strasse 378 DE-93055 Regemsburg, Germany **Analysis and batch release:** M/s Medinova AG Eggbuhlstrasse 28 Zurich, Switzerland **Product License Holder:** Medinova AG Eggbuhlstrasse 28 CH-8050 Zurich Switzerland
	Name of exporting country	Switzerland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 29862 Dated 05/09/2018
	Fee including differential fee	Rs. 50,000/- Dated 05/09/2018

		Rs. 5,000/- dated 19/05/2020 for change of product license holder.
	Brand Name +Dosage Form + Strength	Gynoflor Vaginal tablets
	Composition	Each vaginal tablet contains: Lactobacillus acidophilus……100million cfu Estriol……...0.03mg
	Finished Product Specification	Innovators
	Pharmacological Group	Gynecological anti-infective and antiseptic
	Shelf life	36 months
	Pack size & Demanded Price	1 blister of 6 vaginal tablets, Rs. 1875.
	International availability	Approved in Switzerland as per CoPP and the approval status has been verified from official website. Gynoflor vaginal tablet by M/s medinova, Swissmedic
	Me-too status	Could not be confirmed
	Stability studies	36 months data of 3 batches at 5ºC±3ºC, 60%±5%, Real Time 06 months data of 3 batches at 25ºC± 3ºC, 60%±5%, Acelerated
	Detail of certificates attached	**Original legalized CoPP** **Certificate No**: 20001402 **Certified by**: Swissmedic **Date of issuance:** 20/03/2020 **Free sale:** yes **GMP status:** conforms to WHO-GMP Copy of Distribution agreement is submitted. M/s Medinova AG, Switzerland confirms M/s Zam Zam Pharmaceutical as the exclusive distributor for Pakistan.
	Remarks of the Evaluator.	Lactobaccilus bacilus is a living organism, therefore the content of lactobacillus aciophilus in lyophilisate may vary within the specifications. Manufacturing: 1. Manufacturing of Premix of estriol with cellulose 2. excipients + Acidophilus bacillus lyphilisate Resultant mixtures from both steps ar then finally mixed and compressed.
	Decision: Referred to Committee constituted by DRAP for determining therapeutic group.	
2555.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5744 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SPDROX 500mg capsule
	Composition	Each capsule contains: Hydroxyurea ……500mg
	Finished Product Specification	BP
	Pharmacological Group	antineoplastic (anti-cancer)
	Shelf life	24 Months
	Pack size & Demanded Price	10's & As per SRO
	International availability	Hydroxycarbamide medac 500 mg capsule, hard (Germany)

	Me-too status	HYDREA CPASULES 500MG of M/s BRISTOL MYERS SQUIBB
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2556.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer & marketing authorization holder	M/s SPAL Private Limited Plot No. 12, Biotech Park Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri District, Telangana State-500101, India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5745 Dated 08-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 08-02-2019
	Brand Name +Dosage Form + Strength	SP GEF 250mg tablet
	Composition	Each film coated tablet contains: Gefitinib……250mg
	Finished Product Specification	Firm claim in-house specifications of applied product
	Pharmacological Group	Anticancer
	Shelf life	24 Months
	Pack size & Demanded Price	As per SRO
	International availability	Gefitinib 250 mg film-coated tablets of M/s Cipla (Eu) Ltd., (MHRA approved)
	Me-too status	Could not be confirmed
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 12230/E(M)/TS/2018) issued on 02-10-2018 by Drug Control Administration Govt. of Telangana declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s SPAL Private Limited This certificate is valid until **28-09-2020.** Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	Me too status could not be confirmed.
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2557.	Name and address of Applicant	M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi
	Detail of Drug Sale License	Address: M/s A.J.Mirza Pharma Pvt. Ltd. 1st floor shafi court, Merewether road, civil lines, Karachi Validity: 24-12-2018 to 23-12-2020 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.

	Name and address of marketing authorization holder	M/s Cipla Ltd. S-103 to S-105 S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 & L147/A, Verna Industrial estate, Verna Goa India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7465 Dated 04-07-2017
	Fee including differential fee	Rs. 100,000/- Dated 25-08-2014 copy attached.
	Brand Name +Dosage Form + Strength	Cytodrox Hydroxyurea Capsules USP 500mg
	Composition	Each capsule Contains: Hydroxyurea…….500mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	36 months: Store below 30ºC.
	Pack size & Demanded Price	10's & As per DPC
	International availability	Hydrea 500 mg Hard Capsule by M/s Bristol myer, MHRA Approved.
	Me-too status	Uro-Z 500mg Capsule by M/s Zjans Pharma, Reg. No. 26792
	Stability studies	Firm has submitted long term (36 months) at 30ºC & accelerated (06 months) stability data at 40ºC, 75± 5% RH for three batches.
	Detail of certificates attached	Legalized and valid copy of CoPP Certificate No. 789.MFG/WHO-GMP/DFA/2019/164(2) valid till 19/02/2022 is submitted. The product is available I for free sale in country of origin and the manufactuere conforms to WHO-GMP as per CoPP. Copy of agreement is attached.
	Remarks of the Evaluator.	iii. Photocopy of fee challan form is attached.
	Decision: Approved with as per Policy for inspection of Manufacturer abroad. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
2558.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore
	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020 Address: 73-B Guldashat town, Zarrar Shaheed Road, District Lahore. *the firm has submitted receipt for renewal of license.
	Product License Holder & Manufacturer	M/s S.C. Magistra C&C S.R.L 82A Aurel Vlaicu blvd., Constanta, code 900055, Romania
	Name of exporting country	Romania
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 7571 Dated 28-02-2018
	Fee	Rs. 50,000/- Dated 28-02-2018
	Brand Name +Dosage Form + Strength	Contracept M 18.9mg Pessary
	Composition	Each pessary contains: Benzalkonium chloride……18.9mg
	Finished Product Specification	
	Pharmacological Group	Act code G02BBN2 Local contraceptives
	Shelf life	24 Months
	Pack size & Demanded Price	10's commercial unit & As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed

	Stability studies	Firm has submitted long term (24 months) at 30°C±2°C, 65%RH±5%RH & accelerated (06 months) stability data at 40°C, 75% RH of three batches
	Detail of certificates attached	Legalized and valid copy of CoPP (Certificate#. 5487) issued on 11-10-2017 by Ministry of Health, National Agency for Medicines and Medical Devices declaring the free sale of applied product and GMP compliant status of the manufacturer. Copy of Original Notarized "Product specific Letter of Authorization" from M/s VEM Llac San. Ve Tic. A.S in the name of M/s Bristol Mayer Biotech Pakistan dated 07-06-208 valid for 2 years is submitted
	Remarks of the Evaluator.	vii. The product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP. viii. Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. ix. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the submission of following; • **Calrification is required since the product license holder as per letter of authorization/sole agency agreement is not same as mentioned in CoPP.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech**	

b. Deferred Cases (Human) Import

2559.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Manufacturer & Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3702 Dated 28-01-2019
	Fee including differential fee	Rs. 100,000/- Dated 28-01-2019
	Brand Name +Dosage Form + Strength	DASANIB 70mg Tablet
	Composition	Each film coated tablet contains: Dasatinib…….70mg (as Dasatinib monohydrate 72.58mg)
	Finished Product Specification	In-house
	Pharmacological Group	ANTINEOPLASTIC AGENTS, L01XE Protein kinase inhibitors
	Shelf life	24 Months store below 300C
	Pack size	60's
	International availability	SPRYCEL 70mg (USFDA)
	Me-too status	SPRYCEL 70MG TABLETS of M/s BRISTOL-MYERS SQUIBB,
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.

	Detail of certificates attached	Original Legalized CoPP (Certificate#. 20132019 000767 18) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Valid for twelve months Copy of Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 293rd meeting: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. Submission by the firm: The firm has submitted Original and Valid CoPP (certificate No. 191910) issued by National institute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16599/2020* *Tariff: 6.12.3* *Amount: ARS 300 -* *Date: 01/20/2020* *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2560.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36523 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 100mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……100mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temoeirgen 100Mg Capsules of M/s Merixil Pharma

	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 291st meeting of Registration Board: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. "Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic". Decision: **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP. **Submission by the firm:** The firm has submitted Original and Valid CoPP (certificate No. 191914) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of the certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16598/2020* *Tariff: 6.12.3* *Amount: ARS 300 .-* *Date: 01/20/2020* *Observations* **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2561.	Name and address of Applicant	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Details of Drug sale license	Drug license by way of Wholesale Address: Scilife pharma (pvt) Ltd, P no. FD-57/58-A2, Korangi creek industrial park (KICP) Karachi. Validity: 06/04/2022
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36524 Dated 05-11-2018

	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 250mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……250mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 300C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temonat 250mg Capsules of M/s Hakimsons
	Stability studies	Firm has submitted long term (36 months) at 30oC±20C, 65±5%RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05/18/124543) dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision of 291st meeting of Registration Board: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP. "Now the firm has submitted a copy of letter with English translation from Argentine Republic National Executive Power which shows that "Section 1: To authorize Laboratorio Eczane Pharma S.A to market the Medicinal product Temoxan/Temozolomide 100mg – 250mg Dosage form capsule; certificate no. 57.414, which will be manufacturer at Laboratorio Eczema Pharma S.A., Laprida 431, Avellaneda, Buenos Aires Province, Argentine Republic" **Decision of 293rd meeting:** Deferred for clarification regarding non availability of applied product in country of origin as per submitted CoPP. **Submission by the firm:** The firm has submitted Original and Valid CoPP (certificate No. 191913) issued by National instititute of Drugs Argentina on 09/01/2020. The applied product is available for free sale in the country and the operations and facilities conform to WHO-GMP. Legalization of the submitted CoPP is done on a separate certificate containing content in Spanish language. The firm has provided the official weblink for verification of legalization. The content that is present on the legalized certificate is verifiable from the website but it does not establish any relation of the legalized certificate with the CoPP. The description of one certificate (translated by google translate) is given in the following. *The Legalization Coordination Unit of the Ministry of Foreign Affairs and Worship certifies that the signature that appears in this document: CERTIFICADO DE ANMAT and says Matias Ezequiel GOMEZ (MINISTRY OF HEALTH) is similar to the one in your records.* *Holder / s of the document: LABORATORIO ECZANE PHARMA SA* *Order No: 16597/2020* *Tariff: 6.12.3* *Amount: ARS 300 .-* *Date: 01/20/2020* *Observations* **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad.**	
2562.	Name and address of Applicant	M/s Bristol Mayer Biotech Pakistan, 73-B Guldashat town, zarrar Shaheed road, District Lahore

	Detail of Drug Sale License	License to Sell Drug as Distributor No. 0011000 0001679 valid upto 07-Apr-2020	
	Product License Holder & Manufacturer	M/s VEM Llac San. Ve Tic. A.S. Factory address: Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi. Fatih Bulvari. No: 38 Kapakli/ TEKIRDAG/TURKEY	
	Name of exporting country	Turkey	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy No : 18447 Dated : 21/05/2018	
	Fee including differential fee	Rs : 50,000 Dated : 21/05/2018 + Rs : 50000 :Dated: 16-10-2019	
	Brand Name +Dosage Form + Strength	Candisept 100mg/50ml I.V Solution for Infusion	
	Composition	Each 50ml Vial Contains Fluconazole ……100mg	
	Finished Product Specification	USP	
	Pharmacological Group	Antifungal	
	Shelf life	36 Months	
	Pack size & Demanded Price	As per SRO	
	International availability	Fluconazole 2mg/ml Solution for Infusion (USFDA)	
	Me-too status	Lumen 2mg/Ml Injection (50ml) Of M/S Nimrall Farma (Reg # 039823)	
	Stability studies		
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/1719 **Certified by:** Turkish Medicines and Medical devices Agency *Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey* Product license and date of issue : 254/16 _05.11.2013 **Valid until :** 03-05-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **GMP certificate and Free sale certificate** Certificate No : 2018/1720 Date of Issue: 03-05-2018 Valid until : 03-05/2020 **GMP certificate:** GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **Sole Contract Agreement** 07-06-2018 Validity: 2 Years	
	Remarks of the Evaluator.	**Deficiencies/Shortcomings**	**Reply by Firm**
		Remaining fee of Rs:50000/- as product is already registered in Pakistan.	Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1914215 Dated: 16-10-2019
		Justify use of Type II glass as primary packaging material while in reference agency Type I glass is used as primary packaging material.	According to the European Pharmacopoeia "3.2.1 Glass Containers for Pharmaceuticals Use" Type II glass containers are suitable for most acidic and neutral ,aqueous preparations whether or not for parenteral administration. Our product is near neutral and aqueous

			solution. Therefore, Type II glass is suitable for this product.
	Decision of 293rd meeting: Deferred for Clarification/Justification on scientific grounds for use of Type II glass container as primary packaging material for applied formulation or otherwise evidence of reference product packed in Type II glass container. **Evaluation by PEC:** The firm has provided the reference of the following product approved by MHRA which has been verified with following details; Fluconazole 2 mg/ml Solution for Infusion **2. Qualitative and quantitative composition** 50 ml/100 ml glass vials: 1 ml solution for infusion contains 2 mg of fluconazole. **6.5 Nature and contents of container** Glass vials: Clear type I or II glass vial, sealed with chlorobutyl rubber stopper and sealed with a flip-off aluminium cap. The official website was accessed on 29/06/2020. https://mhraproductsproduction.blob.core.windows.net/docs/c10d2a9d32a84c9c845161dedc2e587247c0ff58 **Decision: Deferred for clarification of DSL details since Form-5A is from M/s Bristol Mayer Biotech whereas renewal application submitted is for M/s. B.M Biotech**		
2563.	Name and address of Applicant	M/s Punjab Medical Services, Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore	
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. OPD Gate sir Ganga ram Hospital Mozang Road Lahore License to sell drugs as a Distributor No. 0011000 0002884 Valid upto 27th Feb. 2021	
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul, 34906, Turkey	
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE	
	Name of exporting country	Greece	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy. No 7371 Dated 20-02-2019	
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019	
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 50mg/vial	
	Composition	Caspofungin Acetate 55.52mg eq. to Caspofungin……50mg	
	Finished Product Specification	In-house	
	Pharmacological Group	Antimycotics for systemic use	
	Shelf life	24 months	
	Demanded Price	As per SRO	
	Pack size	1's	
	International availability	CANCIDAS® 50 mg powder for concentrate for solution for infusion (Netherland)	
	Me-too status	Not available	
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.	
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129338) dated 09-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product	

		License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. **Submission by the firm:** The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland. It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2564.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Mefar Ilac Sana YII A.S., Ramazanoglu Mah. Ensar Cad No: 20, Kurtkoy, Pendik, Istanbul
	Name and address of marketing authorization holder	M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE
	Name of exporting country	Greece
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7370 Dated 20-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 20-02-2019
	Brand Name +Dosage Form + Strength	CASPO PMS, Powder for concentrate for solution for infusion, 70mg/vial
	Composition	Caspofungin Acetate 77.69mg eq. to Caspofungin……70mg
	Finished Product Specification	In-house
	Pharmacological Group	Antimycotics for systemic use
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's
	International availability	CANCIDAS® 70 mg powder for concentrate for solution for infusion (Netherland)
	Me-too status	Not Available
	Stability studies	Firm has submitted long term (24 months) at 5±3oC & accelerated (06 months) stability data at 25+ 2oC for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 129337) dated 08-01-2019 by National Organization for Medicines (EOF) 284 Mesogeion Ave. 15562 Holargos Attica, Greece declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayi A.S. Ramazanoglu Mah. Ensar Cad. No: 20 34906 Kurtkoy-Pendik/ Istanbul Original product specific Letter of Authorization dated 8th January 2019 to importer M/s Punjab Medical Services with Product

		License Holder M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands
	Remarks of the Evaluator.	As per CoPP product license holder M/s Pharmathen International S.A, International Park Sapes Rodopi Prefecture, Block No 5, Rodopi, 69300, GREECE but letter of authorization from M/s Pharmathen Global B.V. located at Van Heuven Goedhartlaan 9, 1181 LE, Amstelveen, Netherlands. Initially in form 5A firm have mentioned "do not store above 30^0C while submitted real time stability data at 2-80C. now firm submit revised form-5A without any fee.
	Decision of 293rd meeting: Deferred for submission of Letter of Authorization from Product License Holder. Submission by the firm: The firm ha submitted copy of Letter of Authorization, the contents of which are similar to that of letter of authorization submitted earlier except the name of and address of the authorizing agen i.e M/s Pharmathen International S.A located at industrial park sapes rodopi prefecture, block number 5, ropdopi 69300, Greece instead of M/s Pharmathen Global B.V. located at Van Heuven goedhartlaan 9, 1181 le,Amstelveen, Netherland. It is also pertinent to mention that the signing authority on both the letters is same. Moreover, the stamp on the letter submitted earlier clearly mentions Amsterdem while the stamp on recently submitted letter is not clear to verify the contents. **Decision: Deferred for further deliberation regarding authenticity of submitted documents.**	
2565.	Name and address of Applicant	M/s Mehran International 498 C Hume Road Quaideen Colony Opp: World Map Near 3 Star Hall Karachi-Pakistan
	Manufacturer & Product License Holder	M/s Hebei New Century Pharmaceutical Co. Limited 189 Taihang Street, Hi-tech zone Shijiazhuang, Hebei, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 31413 Dated 18-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-09-2018
	Brand Name +Dosage Form + Strength	Cefquinome Oral Suspension 2.5% 100ml
	Composition	Each ml contains: Cefquinome sulfate…….25mg
	Finished Product Specification	Firm claim innovators specification
	Pharmacological Group	fourth-generation cephalosporin antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1x100ml bottle Oral Suspension
	RRA status	Combactan of MSD USA
	Stability studies	Firm has submitted long term (36 months) at 30+2oC, 65+5%RH & accelerated (06 months) stability data at 40+ 2oC, 75+ 5% RH for three batches.
	Detail of certificates attached	Copy of CoPP is submitted Copy of Provided Sole agency agreement with M/s NINHUA Group Co., Ltd, 21 Jiangxia st. Ningbo, P.R. China which is sole and exclusive exporting subjected products of the manufacturer in Pakistan and manufacturer shall not sell the above-mentioned items to Pakistan marketed by itself or through any other third parties.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for submission of original legalized CoPP from concerned regulatory Authority of exporting country. Submission by the firm:	

	The firm has submitted original legalized CoPP (no.2019121601) issue dby Agricultural office of Shijiazhuang High-tech zone, China on 16/12/2019. The product is available in free sale. The facilitie and operations conform to WHO-GMP. **Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.**

Miscellaneous deferred cases of Import (Human)

Registration Board in 295th meeting had decided to defer the below mentioned 5 cases and decided that the Secretary Registration Board will confirm from the manufacturer (M/a Shanxi PUDE Pharmaceutical Co., Ltd., MAH Holder) via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.

The reply received from the relevant firm is being reproduced hereby before the Board.

1.

---------- Forwarded message ---------

From: **普德** <pudepharma@yeah.net>

Date: Thu, 3 Sep 2020, 12:46 pm

Subject: Confirmation of Authenticity of Stability Data

To: <abroabdullah@gmail.com>

Dear Abdullah,

Thanks for your email. We confirmed stability data of products for the batches mentioned in below mentioned table is true.

Sr.#	Brand name & Composition	Stability Batch No. & Manufacturing Date
1.	METHOTREXATE for IV injection 50mg/vial Each vial contains: Methotrexate…. 50mg	Batch No: 1845027 Mfg date: June 5, 2017 Batch No: 1845028 Mfg date: June 6, 2017 Batch No: 1845029 Mfg date: June 07, 2017
2.	METHOTREXATE for IV injection 100mg/vial Each vial contains: Methotrexate…. 100mg	Batch No: 19456620 Mfg date: July 09, 2017 Batch No: 19456621 Mfg date: July 10, 2017 Batch No: 19456622 Mfg date: July 11, 2017
3.	METHOTREXATE for IV injection 500mg/vial Each vial contains: Methotrexate…. 500mg	Batch No: 2010100 Mfg date: Aug 15, 2017 Batch No: 2010101 Mfg date: Aug 16, 2017 Batch No: 2010102 Mfg date: Aug 18, 2017
4.	VINORELBINE 10mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg	Batch No: 21000401 Mfg date: Sep 15, 2017 Batch No: 21000402 Mfg date: Sep 16, 2017 Batch No: 21000403 Mfg Date: Sep 17, 2017
5.	VINORELBINE 50mg Lyophilized powder for injection Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg	Batch No: 21000404 Mfg date: Sep 18, 2017. Batch No: 21000405 Mfg date: Sep 19, 2017. Batch No: 21000406 Mfg Date: Sep 19, 2017.

Best regards

Shanxi PUDE Pharmaceutical Co., Ltd Submitted for consideration of the Board.		
2566.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3555 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 50mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 50mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: i. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true j. Detail of diluent to be used for reconstitution. k. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. l. Original, legalized and valid CoPP Evaluation by PEC: i. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (1845027 Mfg date:June5, 1845028 Mfg date: June 6, 2017, 1845029 Mfg	

	date:June 07 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. j. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. k. The product approved in USFDA with same strength and dosage form that is 50mg Powder For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 50mg/2ml solution for injection is approved in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. l. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2567.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3556 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 100mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 100mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for:	

	g. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true h. Detail of diluent to be used for reconstitution. i. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: i. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (19456620 Mfg date:July 09, 19456621 Mfg date: July 10, 2017, 19456622 Mfg date: July 11, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. j. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. k. The product approved in USFDA with same strength and dosage form that is 100mg For injection is discontinued and reason for discontinuation is not mentioned on the official website of the authority while 100mg/4ml solution for injection is available in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. l. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2568.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3558 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 500mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 500mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	

	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150011) issued by Shanxi Food and Drug Administration valid till 03/11/***2017*** *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: g. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true h. Detail of diluent to be used for reconstitution. i. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: i. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (2010100 Mfg date: Aug 15, 2010101 Mfg date: Aug16, 2017, 2010102 Mfg date: Aug 18, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. j. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. k. The product (500mg for injection) with same strength and dosage form is not available in reference authorities while 500mg/20ml solution for injection is discontinued for reasons other than safety and efficacy. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. l. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2569.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 395 Dated 16-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 15-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 10mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years

	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 10mg/ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 10mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: k. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true l. Detail of diluent to be used for reconstitution. m. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. n. The salt form of the drug as it is different from the approved product in reference countries. o. Finished product specifications. Evaluation by PEC: m. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. n. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection. o. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted. p. Firm submitted CFDA standard specification. q. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000401 Mfg date: Sep 15, 2017, 21000402 Mfg date: Sep 16, 2017, 21000403 Mfg Date: Sep 17, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. r. Salt form	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved with innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2570.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3560 Dated 06-03-2017

	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 50mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer*.
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 50mg/5ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 50mg/vial.

Decision of 274th meeting of Registration Board: Registration Board deferred the cases for:

m. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true
n. Detail of diluent to be used for reconstitution.
o. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
p. The salt form of the drug as it is different from the approved product in reference countries.
q. Finished product specifications.
r. Sole agency agreement

Evaluation by PEC:

m. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL.
n. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection.
o. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted.
p. Firm submitted CFDA standard specification.
q. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000404 Mfg date: Sep 18, 2017, 21000405 Mfg date: Sep 19, 2017, 21000406 Mfg Date: Sep 19, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data.
r. Salt form

Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.

Decision: Approved with innovators specifications as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.

Registration Board in 295th meeting had decided to defer the below mentioned 02 cases and decided Secretary Registration Board will confirm from the manufacturer via email regarding the authenticity of submitted stability data. Accordingly, the Secretary Registration Board communicated with the firm regarding the submitted stability data of relevant batches.

The reply received from the relevant firm is being reproduced hereby before the Board.

Dear ABDULLAH

Sorry for my late reply.

we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg: Each ampoule (2mL) contains: Irinotecan hydrochloride trihydrate……40mg	19277800	Oct 20, 2017
		19277801	Oct 21, 2017
		19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg: Each ampoule (5mL) contains: Irinotecan hydrochloride trihydrate……100mg	19277803	Oct 23, 2017
		19277804	Oct 24, 2017
		19277805	Oct 25, 2017

Please see attachment for STATEMENT.

Best regards!

Anna

Cisen Pharmaceutical Co., Ltd.

Add: Tongji Sci-tech Industrial Park, High-tech Industrial Development Zone, Jining, Shandong, P.R. China. 272073

Tel: +86 537 2980071 +86-18678761518

---------- Original ----------

From: "wangsh"<wangsh@cisengroup.com>;

Date: Sat, Aug 29, 2020 04:52 PM

To: "Abdullah Abro"<abroabdullah@gmail.com>;

Cc: "selina"<selina@nbpharm.com>; "shirlyran"<shirlyran@nbpharm.com>; "Obaidullah Malik"<obaiddr@yahoo.com>;

Subject: Re:Confirmation of Authenticity of Stability Data

Aug.31, 2020

STATEMENT

To whom it may concern,

Hereby, we (Cisen Pharmaceutical Co. Ltd.) confirm that the stability data of IRINOTECAN INJECTION 40mg/2mL and IRINOTECAN INJECTION 100mg/5mL with the following information was submitted by our company.

Sr.	Brand Name & Composition	Stability Batch No.	Manufacturing Date
1.	IRINOTECAN injection 40mg:	19277800	Oct 20, 2017
	Each ampoule (2mL) contains:	19277801	Oct 21, 2017
	Irinotecan hydrochloride trihydrate……40mg	19277802	Oct 22, 2017
2.	IRINOTECAN injection 100mg:	19277803	Oct 23, 2017
	Each ampoule (5mL) contains:	19277804	Oct 24, 2017
	Irinotecan hydrochloride trihydrate……100mg	19277805	Oct 25, 2017

Sincerely yours,
Quality Management Department

For and on behalf of
Cisen Pharmaceutical Co. Ltd.

2571.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 40mg
	Composition	Each ampoule (2ml) contains: Irinotecan…… 40mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066186)

	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/62246) issued by Jining Food and Drug Administration valid till 14/12/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted (dated 15th August 2017, and after that on dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (2ml) contains: Irinotecan…… 40mg CoPP valid till 14-12-2017 Copy of valid DSL Composition different from reference?	
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (19277800 Mfg date: Oct 20, 2017, 19277801 Mfg date: Oct 21, 2017, 19277802 Mfg Date: Oct 22, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 14/12/2017.	
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**	
2572.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.

		Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 100mg
	Composition	Each ampoule (5ml) contains: Irinotecan…… 100mg
	Finished Product Specification	(USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066187)
	Stability studies	
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/47074) issued by Jining Food and Drug Administration valid till 16/09/2017 **declaring the free sale of applied product and GMP compliant status of the manufacturer.**
	Remarks of the Evaluator.	The firm has claimed In House manufacturing specifications and the product is present in USP. The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true Detail of diluent to be used for reconstitution. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: In response to decision of Registration Board the firm has submitted data dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. Reference formulation is Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (5ml) contains: Irinotecan…… 100mg CoPP valid till 16-09-2017	
	Evaluation by PEC: The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved.	

	The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (1977803 Mfg date: Oct 23, 2017, 19277804 Mfg date: Oct 24, 2017, 19277805 Mfg Date: Oct 25, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. COPP is not valid and was expired on 16/09/2017.
	Decision of 295th meeting: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data. **Decision: Approved as per Policy for inspection of Manufacturer abroad. Stability data will be verified by panel during inspection of the firm.**

c. New cases (Import) Veterinary

2573.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Drug Sale License	M/s Geevet International Naz Medicine Market Namak Mandi Peshawar Whole sale / distributor Valid till 01/01/2022.
	Name and address of manufacturer	**Manufacturer and MAH:** M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27773 Dated 13-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 13-08-2018
	Brand Name +Dosage Form + Strength	Lincocid Gold soluble powder
	Composition	Each gram contains: Spectinomycin base…..444mg Lincomycin base……..222mg
	Finished Product Specification	Chinese Pharmacopoeia
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1kg, 500gm, 250gm
	Me-too status	LINCO-S 100 W/S POWDER by M/s Attabak, Reg. No. 062169
	Stability studies	Firm has submitted long term (24 months) at 30°C 65% RH & accelerated (06 months) stability data at 40°C, 75% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (Certificate#. 05019)** Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023 Copy of sole agency agreement is submitted.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2574.	Name and address of Applicant	M/s Qualivet Pharma, No.5/15, Ground Floor, Survey No.79, Golden town, Karachi.
	Detail of Drug Sale License	**Address:** M/s Qualivet Pharma, H.No. 5/15 Groud floor, survey no.79 golden town Karachi. **Validity:** 26-11-2019

		Status: License to sell, stock & exhibit for sale, distribute and sell drugs by way of WHOLE SALE by manufacturer, importer or intender.
	Name and address of manufacturer	M/s Laboratory Karizoo SA, , Mas Pujades, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain.
	Name and address of marketing authorization holder	M/s Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 32632 Dated 01-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 01-10-2018
	Brand Name +Dosage Form + Strength	LEVOFLOK 100mb/ml Oral Solution
	Composition	Each ml contains: Enrofloxacin……..100mg
	Finished Product Specification	Mfg specs
	Pharmacological Group	Abtibacterial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	250ml, 1Litre, 5Litre
	International availability	Available in Spain for free sale as per CoPP
	Me-too status	ROXIN 10% ORAL SOLUTION by M/s M&H PHARMACEUTICALS LAHORE (Imported) Reg. No. 015495
	Detail of certificates attached	**<u>Original Legalized CoPP:</u>** **Certificate No:** Nil **Certifying Authority:** Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Issue Date:** 10/05/2018 **Free sale in exporting country:** Yes **Applicant of certificate:** Vetpharm animal Health, S.L. Les Corts, 23 08028 Barcelona, Spain. **GMP:** • **<u>Original legalized GMP Certificate</u>** **Certificate no.** ES/135HV/19 **Manufacturer Address:** M/s Laboratory Karizoo SA, Mas Pujades, 5-10, 11-12, Pol. Ind. La Borda, caldes de Montbui, 08140, Barcelona, Spain. **Issued by:** Agencia Espanola De Medicomentos Y productos Sanitarios, SPAIN **Status:** valid till 23/04/2022
	Remarks of the Evaluator:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Moreover the applicant will provide the valid copy of Drug sale License.	
2575.	**Name and address of Applicant**	M/s Hassan Brothers House No. 318 St. # 6 Fatehabad Sharqi, Satiana Road Faisalabad
	Detail of Drug Sale License	M/s Hassan Brothers Ground floor P. 318 St. # 6 Mohallah Fateh abad Sharqi, Satiana Road Faisalabad License to sell drugs as a distributor No: 0011000 0001570 valid upto *29-March-2020. *The firm has submitted the receipt for renewal of DSL dated 24/06/2020.
	Product License Holder & Manufacturer	Head office: M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea Factory: M/s Samyang Anipharm co. Ltd. 35, Songseon-ro 265 beon-gil, Pocheon-si, Gyconggi-do, Korea

	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 42885 Dated 17-12-2018
	Fee including differential fee	Rs. 100,000/- Dated 17-12-2018
	Brand Name +Dosage Form + Strength	FLOCOL-200 SOLUTION
	Composition	Each ml contains: Florfenicol….200mg
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Pack size & Demanded Price	500ml, 1L, 2.5L & 5L
	International availability	Korea
	Me-too status	TEMPRO-20% LIQUID by M/s Ras Pharma, Reg. No. 96838
	Stability studies	Real Time data for 24 months Accelerated data for 6 months as per Zone-IVA submitted.
	Detail of certificates attached	• Original Legalized FSC (Certificate#. M1813617) issued on 02-10-2018 by Animal and Plant Quarantine Agency Korea declaring the free sale of applied product in country of origin Korea. • Original Legalized GMP issued by Animal and Plant Quarantine Agency Korea dated 02-10-2018. • Original sole agency agreement is submitted. M/s Samyang Anipharm co. 6-5, Tongil-ro 83-gil, Eunpyeong-gu, seoul, Korea appointed M/s Hasssan Brothers Faisalabad as Distributor for Pakistan for the applied product.
	Remarks of the Evaluator.	
	Decision: Approved as per policy for inspection of manufacturer abroad.	

2576.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 25112 Dated 19-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-07-2018
	Brand Name +Dosage Form + Strength	Bravecto 1000mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.

	Remarks of the Evaluator.	The submitted stability data contains the results of only initial time point. Submit 06 months accelerated stability and 24 months real time stability study data according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2577.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21640 Dated 20-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 20-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 112.5mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……112.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	

2578.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 21052 Dated 12-06-2018
	Fee including differential fee	Rs. 100,000/- Dated 08-06-2018
	Brand Name +Dosage Form + Strength	Bravecto 250mg Chewable tablets for dogs
	Composition	Each Chewable table contains: Fluralaner……250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product.
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2579.	Name and address of Applicant	M/s Vety care (pvt) ltd. 4-A, block A Satelite town Rawalpindi.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer:** Intervet GesmbH, Siemensstrasse 107, 1210, Vienna, Austria. **Marketing Authorization Holder:** M/s Intervet International B.V., Wim de Korverstraat 35, 5831 An Boxmeer, the Netherlands.
	Name of exporting country	The Netherlands
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 17307 Dated 10-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-05-2018
	Brand Name +Dosage Form + Strength	Bravecto 500mg Chewable tablets for dogs
	Composition	Each Chewable table contains:

		Fluralaner……500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	Could not be confirmed.
	Stability studies	
	Detail of certificates attached	Copy of certificate of a veterinary medicinal product (112.5mg, 250mg, 500mg, 1000mg, 1400mg) certificate no. 05/17/110419 issued by EMA on 28/06/2017, the applied product is in the market of exporting region. The facilities and operation conform to WHO-GMP.
	Remarks of the Evaluator.	Submit real time stability data till shelf life and 06 month accelerated stability data of 03 batches according to the conditions of zone IV-A. Product specific sole agency agreement is required to be submitted. Submit original legalized and valid CoPP/medicinal product certificate. Give detail of pack size of the applied product. Me-too status of the product
	Decision: Deferred for submission of the following; • **Submission of 06 months accelerated stability and 24 months real time stability study data of 03 batches according to the conditions of zone IV-A.** • **Product specific sole agency agreement is required to be submitted.** • **Submission of original legalized and valid CoPP/medicinal product certificate.** • **Detail of pack size of the applied product.**	
2580.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9004 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Reefmox oral powder 50%
	Composition	Each gram contains: Amoxicillin trihydrate…… 500mg
	Finished Product Specification	
	Pharmacological Group	Antiobiotic
	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00079. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement.

		Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decsion: Deferred for the following: • **Provide product specific sole agency agreement.** • **Clarification is required since the Qc testing of the applied product is done according to the In-House standard while the product is present in British Pharmacopoeia (B.P). Moreover, the assay is performed for Amoxicillin Trihydtrate while the content of Amoxicillin (base) should be determined considering the prescribed assay limits according to B.P, clarify.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2581.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9002 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Neoreef 500 oral powder
	Composition	Each gram contains: Neomycin sulphate…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic
	Shelf life	36 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00078. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.

	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license**.	
2582.	Name and address of Applicant	M/s Meezab Z International Company, Fareed Abad near Bilal Mosque, Jahanian, Punjab.
	Detail of Drug Sale License	Drug License by way of
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Al Reef company for manufacturing Veterinary Drugs & Agrichemicals (REEFCO), Alhassan Industrial Estate, Irbid, Jordan.
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 9003 Dated 28/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 27/02/2019
	Brand Name +Dosage Form + Strength	Reedox 500 oral powder
	Composition	Each gram contains: Doxycycline HCl…… 500mg
	Finished Product Specification	In House
	Pharmacological Group	Antiobiotic
	Shelf life	24 months
	Pack size & Demanded Price	Price decontrolled
	Me-too status	
	Stability studies	36 months real time and 06 months accelerated stability study data of 03 batches is submitted. (HDPE jar).
	Detail of certificates attached	Original legalized Free Sale Certificate issued by Ministry of Agriculture , Veterinary Directorate, Jordan on 04/01/2017 certificate no. 00077. The product is registered and freely sold in exporting country as per the certificate. Original legalized GMP certificate issued by Director of Veterinary & Animal Health on 09/12/2018.
	Remarks of the Evaluator.	Provide product specific sole agency agreement. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Clarification regarding the pack size is required. Provide valid copy of Drug Sale license.
	Decision: Deferred for the following; • **Provide product specific sole agency agreement.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Clarification regarding the pack size is required.** • **Provide valid copy of Drug Sale license.**	
2583.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor

		Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain **Exporter:** MPA Vetrinary Medicines and Additives S.L. C/Mogoda, 16-18 Pol. Ind. Can Salvatella. Barbera del Valles. Barcelona, Spain.
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 4657 Dated 01/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Linesvall 150mg/ml solution for injection
	Composition	Each ml contains: Lincomycin as hydrochloride……..50mg Spectinomycin as sulphate tetrahydrate…….100mg
	Finished Product Specification	In House
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml vial, Price decontrolled
	Me-too status	BIO-LINCO-S INJECTION. 200/50mg per ml by M/s International chempharma Reg. No. 39967
	Stability studies	36 months data according to the conditions of zone IV-A of 3 batches is submitted. Accelerated data is not submitted.
	Detail of certificates attached	Legalized Free sale certificate issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2584.	Name and address of Applicant	M/s Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Cherry Pharmceutica International, 14-E, Ground floor/basement, Punjab cooperative housing society, Ghazi road Lahore. Validity: 20/12/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Mevet S.A.U. Poligono Industrial El Segre, nº 409-410 y CP 25191 LLEIDA, Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 4658 Dated 01/02/2019

	Fee including differential fee	Rs. 100,000/- Dated 01/02/2019
	Brand Name +Dosage Form + Strength	Tilovall 200mg/ml solution for injection
	Composition	Each ml contains: Tylosin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Pack size & Demanded Price	Price decontrolled, 100ml vial
	Me-too status	BILOSIN 200MG/ML SOLUTION FOR INJECTION by M/s Binsadiq International, Reg. no. 84841
	Stability studies	24 months real time, 06 months accelerated stability
	Detail of certificates attached	Legalized Free sale certificate for Tilovall 200mg/ml issued by Agencia espanola de medicamentos y productos sanitorios (AEMPS) issued on 08/06/2018 confirms the free sale of the product in exporting country. Copy of GMP certificate no. ES/123HV/18 issued by AEMPS, inspection date 12/07/2018. Original Legalized Agency Agreement is submitted. The Principal (Manufacture and Exporter) authorized M/s Cherry Pharmaceutica International as distributor (exclusive agent) for Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
2585.	Name and address of Applicant	M/s ZS Biotech Animal Health Company. 50-C Madina Block Awan Town Multan Road, Lahore.
	Detail of Drug Sale License	License to sell drugs as a Distributor Address: Validity:
	Manufacturer & Product License Holder	**Manufacturer & MAH:** Farmabse Saude Animal Ltda Av. Emilio Marconato, n^{o} 1000-Galpao A-Jaguariuna (SP) Brazil.
	Name of exporting country	brazil
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 2972 Dated 23/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 23/01/2019
	Brand Name +Dosage Form + Strength	Farmadox 50 oral powder
	Composition	Each 100 gram contains: Doxycycline hyclate……. 50gm
	Finished Product Specification	
	Pharmacological Group	tetracycline
	Shelf life	2 years
	Pack size & Demanded Price	200gm & 25kg, price decontrolled
	Me-too status	
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Original and legalized free sale certificate is submitted while legalized free sale with English translation is required. As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify. Submit 06 months accelerated stability studies of 03 batches. Valid copy of Drug Sale License is required.

		Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following; • **Original and legalized free sale certificate is submitted while legalized free sale with English translation is required.** • **As per submitted SmPC, the applied formulation contains "Doxycycline As Hyclate" while according to the free sale certificate and form 5A, the product contains "Doxycycline Hyclate", clarify.** • **Submit 06 months accelerated stability studies of 03 batches.** • **Valid copy of Drug Sale License is required.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2586.	Name and address of Applicant	M/s Orient Animal Health (pvt) ltd. Commercial #6, Block-A, 1st floor, Kazimabad, Near Masjid e Hira, Model Colony, Karachi.
	Detail of Drug Sale License	Drug License by way of wholesale Address: Orient Animal Health (PVT) LTD. Comm-6 Block-A Ist floor Kazimabad, Model Colony Karachi. Godwon: Ground floor C-14 Block-A Kazimabad Model Colony Karachi. Validity: 22/10/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Univet Ltd., Tullyvin, Cootehill, County Cavan, H16 T183 , Ireland.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 1689 Dated 14/01/2019
	Fee including differential fee	Rs. 100,000/- Dated 14/01/2019
	Brand Name +Dosage Form + Strength	Solu-Flox 100mg/ml solution for use in drinking water
	Composition	Each ml contains: Enrofloxacin…… 100mg
	Finished Product Specification	In House
	Pharmacological Group	Anti bacterial
	Shelf life	3 years
	Pack size & Demanded Price	100ml, 1 litre, 5 litre, price decontrolled
	Me-too status	ENROFLOX SOLUTION (10gm/100ml) by M/s Biorex, Reg. No. 031528
	Stability studies	
	Detail of certificates attached	
	Remarks of the Evaluator.	Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate. Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.
	Decision: Deferred for the following: • **Submit original, legalized and valid CoPP/free sale certificate and valid copy of GMP certificate.** • **Stability study data of 36 months real time and 06 months accelerated of 03 batches according to the conditions of zone IV-A.**	

	• **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **The applied product is Oral Solution to be used with drinking water while the product is present in USP as Oral Suspension, clarify.**	
2587.	Name and address of Applicant	M/s HPI Pharma, Bao wala Opposite truck stand gate no. 2 Rasheed Abad, Jhang Road Faisalabad.
	Detail of Drug Sale License	Drug License by way of wholesale Address: HPI Pharma, Ground floor P-171 Medol Town-B, District Faisalabad. Karachi. Validity: 08/08/2020
	Manufacturer & Product License Holder	**Manufacturer & MAH:** M/s Industrial Veterinaria, S.A Esmeralda 19, 08950 Espulgues de Llobregat Barcelona, Spain.
	Name of exporting country	spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 5170-B Dated 06/02/2019
	Fee including differential fee	Rs. 100,000/- Dated 06/02/2019
	Brand Name +Dosage Form + Strength	Pluscolan concentrate for oral solution
	Composition	Each ml contaions: Colistin sulfate……..5,000,000 IU
	Finished Product Specification	In house
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Pack size & Demanded Price	100ml, 1litre, 5litre, price decontrolled
	Me-too status	
	Stability studies	24 moths real time and 06 months accelerated of 3 batches as per ZONE IV-A.
	Detail of certificates attached	Original legalized free sale certificate issued on 06/07/2018, the product is freely sold in exporting country and the manufacturer conforms to WHO-GMP as per the certificate.
	Remarks of the Evaluator.	Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only. Submit drug product specification data in the light of decision of Registration Board in its 267th meeting. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Clarification is required since the submitted documents (free sale certificate and stability study data) along with the dossier show that the applied product contains Colistin Sulfate (in terms of international units IUs) while the calculation of IU's is based upon the activity of base only.** • **Submit drug product specification data in the light of decision of Registration Board in its 267th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

d. Case no. 4: Deferred cases (Import) Veterinary

2588.	**Name and address of Applicant**	**M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore**
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria

		(QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Vetmulin 450mg/g Water soluble granules
	Diary No. Date of R& I & fee	Dy No. 336 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Tiamulin hydrogen fumarate ……450 mg
	Target Specie	Chicken, Turkey
	Pharmacological Group	ATC Vet Code: QJ01XQ01 Antibacterials for systemic use, Pleuromutilins
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years (supported by accelerated and real time stability data)
	Pack size & Demanded Price	1 kg sachet
	Approval status of product in Reference Regulatory Authorities.	Vetmulin (Denmark Approved) HPRA Approved
	Me-too status	006846 TIAMUTIN 45% HILTON KARACHI
	CoPP/GMP status	**Original, legalized certificate of origin and free sale** issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale **Copy of GMP certificate** (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food **Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria**
	Remarks of the Evaluator.	**Withdrawal Period:** Chickens Meat and offal: 3 days Eggs: Zero days Turkeys Meat and offal: 5 days ● The address of manufacturing site on GMP certificate is "39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria" which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag.

	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate. Decision of 285th meeting of Registration Board: "Deferred for above clarifications" Now the firm has submitted the following documents: g. Vetmulin 450mg/g It is a 1kg sachet. h. Original Legalized CoPP (Certificate#. BG 6/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria) i. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2589.	**Name and address of Applicant**	M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) **48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufactures)**
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria
	Brand Name +Dosage Form + Strength	Tilmovet 250mg/ml Concentrate for oral solution

	Diary No. Date of R& I & fee	Dy No. 337 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each ml contains Tilmicosin ……250 mg
	Target Specie	Chicken (Broiler, pullets), Turkey and Calves
	Pharmacological Group	Antimicrobials for systemic use, macrolides ATC vet code: QJ01FA91
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Shelf life	2 years
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Pack size & Demanded Price	960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper-evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET. 60 mL PET vials with closure of PET/PE
	Approval status of product in Reference Regulatory Authorities.	HPRA Approved
	Me-too status	044909 HICOS 250 ORAL SOLUTION HILTON PHARMA (PVT) LTD., KARACHI.
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale Copy of GMP certificate (No. 31/2013/GMP) issued on 27-12-2013 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate
	Remarks of the Evaluator.	Withdrawal Period: Calves: 42 days. Chickens: 12 days Turkeys: 19 days Eggs: Not authorized for use in birds producing eggs for human consumption. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD.
	Previous Decision (M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder **mentioned on Form 5A. Clarification is required.**

Fresh Evaluation:

a. **Clarification for type of container whether you have applied for sachet or bag.**

960 ml is presented in a white high density polyethylene bottle with white polypropylene or , tamper evident cap, 240 ml is presented in high density polyethylene (HDPE) bottle with a closure made of PET.60 mL PET vials with closure of PET/PE.

b. **The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence.**

(QC and Batch Release+Headquarter)

Biovet Joint Stock Company
39, Petar Rakov St. 4500 Peshtera, Bulgaria

(Manufactures)

48 Vasil Petleshkov Str Peshtera 4550,Bulgaria

c. **The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.**

Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale certificate.

Decision of 285th meeting of Registration Board:

"Deferred for above clarifications"

Now the firm has submitted the following documents:

g. Tilmovet 250mg/ml concentrate for oral solution is packed in 3 container types and sizes:
   High density polyethylene (HDPE) bottles of 960ml with vertically see-through bar and a graduated scale provided with white tamper evident closure made of PP with white foamed sealing disk.
   High-density polyethylene (HDPE) bottles of 240ml with a closure made of polyethylene terephthalate (PET).
   Polyethylene terephthalate (PET) vials of 60ml with a closure made of polyethylene terephthalate/polyethylene (PET/PE).
   (Provided stability data is of only 240ml bottle)

h. Original Legalized CoPP (Certificate#. BG 7/2019) issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium.
   (Revised form-5A showed that Address of QC, Batch release and Headquarter: 39, Petar Rakov Street, 4550 Peshtera, Bulgaria while address of manufacturing site is 48 vasil Petleshkov street, Peshtera 4550, Bulgaria)

i. The firm has submitted original and legalized letter of authorization for the following products;
   Hydrodoxx 500mg
   Vetmulin 450mg
   Tilmovet 250mg

Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.

2590.		
	Name address of Applicant	M/s Saadat International, 117 Habitat Flat Shadman II Jail Road Lahore
	Drug Sale License	**Address**: 117 Habitat Flat Shadman II Jail Road Lahore Lahore **Validity:** 12-06-2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria (Manufacturer)
	Name and address of Product License Holder	Huvepharma AD, 3a Nikolay Haytov street, 1113 Sofia Bulgaria
	Exporting Country	Bulgaria

	Brand Name +Dosage Form + Strength	HydroDoxx 500mg/g Powder for use in drinking water
	Diary No. Date of R& I & fee	Dy No. 335 : 09-06-2015 PKR 100,000/- : 09-06-2015
	Composition	Each gram contains Doxycycline (as hyclate) ……500 mg
	Pharmacological Group	ATC Vet Code: QJ01AA02.: Antibacterial for systemic use; tetracyclines Tetracycline
	Type of Form	Form 5-A
	Finished Product Specification	Innovator
	Target Specie	Chicken Broiler
	Shelf life	3 years (supported by accelerated and real time stability data) Shelf-life of the veterinary medicinal product as packaged for sale: 36 months(HPRA)
	Pack size & Demanded Price	1kg sachet
	Approval status of product in Reference Regulatory Authorities.	Ireland Approved HPRA
	Me-too status	023470 Doxyveto- 50 S Soluble Powder Vmd Pakistan Rawalpindi
	CoPP/GMP status	Original, legalized certificate of origin and free sale issued on 20-03-2014 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms its free sale. Copy of GMP certificate (No. 64/2017/GMP) issued on 01-13-2017 by Ministry of Agriculture and Food, Bulgarian Food Safety Agency confirms the GMP of Biovet but the address written on certificate is different from that provided in Form 5-A as well as in free sale certificate. Authority letter M/s Saadat International 117 Habitat Flat Shadman II Jail Road Lahore & Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria Dated : 13 June 2017 Biovet Joint Stock Company is subsidiary of Huvepharma Eood Located in 3 A ,Nikolay haytov Street, Sofia, 1113 , Bulgaria
	Remarks of the Evaluator.	Withdrawal Period: Meat and offal: Chicken : 6 days Not authorized for use in laying birds producing eggs for human consumption Do not use within 4 weeks of onset of the laying period. ● The address of manufacturing site on GMP certificate is 39, Petar Rakov St. 48 Vasil Petleshkov Str Peshtera 4, Pazardjik, Bulgaria which is different from that provided on Form 5-A . ● The free sale certificate mentions the product license holder is Biovet Joint Stock Company whereas Form 5 A mentions Huvepharma AD. ● Clarify 1 Kg sachet or bag
	(M-282)	Deferred for the following reasons: ● Clarification for type of container whether you have applied for sachet or bag. ● The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP

		certificate. Clarification is required with documented evidence. ● The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required.
	Fresh Evaluation: a. Clarification for type of container whether you have applied for sachet or bag. 1 Kg sachet b. The address of manufacturing site mentioned on Form 5A is different from the address mentioned on GMP certificate. Clarification is required with documented evidence. (QC and Batch Release+Headquarter) Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (Manufactures) 48 Vasil Petleshkov Str Peshtera 4550,Bulgaria c. The product license holder mentioned on free sale certificate is different from the product license holder mentioned on Form 5A. Clarification is required. Firm has submitted that product license holder is Biovet Joint Stock Company 39, Petar Rakov St. 4550 Peshtera, Bulgaria and the same has been mentioned on Free sale Certificate.	
	Decision of 285th meeting of RB: Deferred for above clarifications Now the firm has submitted the following documents: g. It is a 1kg sachet h. **Original Legalized CoPP (Certificate#. BG 5/2019)** issued on 29-01-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., BIOVET Joint Stock Company**, 39 Petar Rakov Str. /48 Vasil Petleshkov Str., Peshtera 4550, Bulgaria**. Product License Holder of applied product is M/s Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium. (Revised form-5A showed that Address of QC, Batch release and Headquarter: **39, Petar Rakov Street,** 4550 Peshtera, Bulgaria while address of manufacturing site is **48 vasil Petleshkov street**, Peshtera 4550, Bulgaria) i. The firm has submitted original and legalized letter of authorization for the following products; Hydrodoxx 500mg Vetmulin 450mg Tilmovet 250mg **Decision: Deferred for confirmation whether the applicant has applied same addresses of manufacturing sites as per CoPP.**	
2591.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26825 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	COLMYC 20% Oral solution for administration in drinking water
	Composition	Each ml contains: Enrofloxacin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	3 years store below 30^0C

	Demanded Price	Decontrolled
	Pack size	500ml, 1L,5L
	Me-too status	EL-FLOXACIN LIQUID of M/s ELKO ORGANISATION,
	Stability studies	Firm has submitted long term (36 months) at 30ºC 75±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 14th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	Applied product is **Suspension as per USP monograph but applied product is solution dosage form**.
	Decision of 292nd meeting of Registration Board: Deferred for following: Applied product is suspension as per USP monograph, but applicant apply solution dosage form. M/s Poul Med submitted that the European Pharmacopoeia monograph number 2229 for Enrofloxacin (Enrofloxacin for veterinary use) is the only monograph available for Enrofloxacin in the European Pharmacopoeia. It describes the tests and specifications that the raw material (enrofloxacin) must follow to comply with the European Pharmacopoeia standards. It does not state that it is for suspension product forms only. Decision of 293rd meeting: Registration Board deferred the application for dosage form clarification. Submission by the firm: The firm has submitted that the dosage form of the applied product is Oral Solution while in USP describes the monograph for Oral Suspension. The firm has requested for grant of registration with innovator's specifications. Moreover, the firm has submitted fee Rs. 5,000/- with the reply (challan number 0539489 dated 22/04/2020). **Decision: Deferred for confirmation of composition of formulation in the database of importing country.**	

Case No. 5: Import cases (Human) Form 5F

2592.	**Name, address of Applicant / Importer**	**M/s** Gene Tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi
	Details of Drug Sale License of importer	**License No:** 10725 **Address:** Gene-tech Laboratories 246/B-P.E.C.H.S. Block-6, Karachi **Validity: ***15-August-2020 **Status:** Drug License By way of Wholesale *The firm has submitted receipt for renewal of DSL dated 24/05/2020.
	Name and address of marketing authorization holder (abroad)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name, address of manufacturer(s)	M/s Nano Fanavaran Darouei Alvand 1462, Pharmaceutical Incubation Center, Avicenna Tech. Park of Tehran University of Medical Sciences, North Kargar Ave., Tehran, Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Legalized CoPP (Certificate Ref. 665/5405)** 20-04-2019 by Ministry of Health and Medical Education declaring the free sale of

		applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Product specific sole agency agreement is submitted.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	Alvocade Single use vial containing 3.5mg powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Bortezomib powder….3.5mg
	Pharmaceutical form of applied drug	Powder for Injection IV/Sc
	Pharmacotherapeutic Group of (API)	Anticancer
	Reference to Finished product specifications	In-House
	Proposed Pack size	1 vial box
	Proposed unit price	73.2 Dollars
	The status in reference regulatory authorities	Bortezomib 3.5 mg powder for solution for injection (UK)
	For generic drugs (me-too status)	Egybort injection by M/s Revive Pharma, Reg. No. 090738
	Module-II (Quality Overall Summary)	The submitted QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Laurus Labs Limited Plot no.21 Jawaharlal Nehru Pharma City, Parawada Visakhapatanma 531021 Andra Pradesh India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted. Real time at -20^{o}C±5^{o}C for 12 months Accelerated study at 5^{o}C±3^{o}C for 6 months

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted comparative table summarizing results of all physico-chemical tests performed on 5 batches of applied product and one batch of the reference product i.e. Omnipaque injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 12 months.
	Evaluation by PEC:	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2593.	**Name, address of Applicant / Importer**	**M/s** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad
	Details of Drug Sale License of importer	**License No:** DSL-002-ICT/2013 **Address:** Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad **Address of Godown:** Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. **Validity:** 30/01/2022 **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	**Manufacturing site:** **Site responsible for batch release, primary and secondary packaging:** M/s ILDONG Pharmaceutical co., ltd. 25, gongdan 1-ro, Anseong-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	Korea

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original Legalized CoPP (Certificate#. 2019-D1-0700) by Ministry of Food and Drug Safety declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s ILDONG Pharmaceutical co., ltd. Korea. Issued date: Mar. 15, 2019
	Details of letter of authorization / sole agency agreement	Authorization letter by manufacturer M/s ILDONG Pharmaceutical co., ltd. In the name of importer M/s Amgomed registration, sale and distribution in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7963 Dated 10-06-2019
	Details of fee submitted	Rs. 100,000/- Dated 29-05-2019
	The proposed proprietary name / brand name	SPECSSA Tablet 250mg (Gefitinib)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Gefitinib……..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anticaner
	Reference to Finished product specifications	In house
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**IRESSA of USFDA**
	For generic drugs (me-too status)	Gefticip 250mg Tablet of M/s AJMs
	Module-II (Quality Overall Summary)	Submitted. The QOS is as per WHO-PD template.
	Name, address of drug substance manufacturer	M/s Mac chem Products (India) Pvt. Ltd. N-211/2/10. Tarapur MIDC.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time at 30°C±2°C & 65%RH±5% of 3 batches for 24 months Accelerated at 40°C±2°C & 65%RH±5% of 3 batches for 24 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVC blister and hard foil
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 36 months.
	Evaluation by PEC:	
	Decsion: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
2594.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16455 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 5ml contains: Paclitaxel……30mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	antineoplastic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Paclitaxel Injection 30mg/5Ml of M/s Innopharm Karachi
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted pharmaceutical equivalence against the innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC-I:		
Decision: Deferred for clarification regarding storage conditions of stability study data of finished product which is not as per Zone IVA.		
2595.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16457 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 16.7ml contains: Paclitaxel……100mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	Ebetaxel 100mg/16.7Ml Injection M/s Bio Pharma
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		
2596.	Name, address of Applicant / Importer	**M/s** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	**Drug License by the way of Wholesale** **License No:** 0865 **Address:** Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. **Validity:** 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	**Manufacturer:** M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China **Batch Releasing site:** M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	Name of exporting country	UK

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP for Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (Certificate#. PP10161139) dated 16-05-2019 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 16456 Dated 02-09-2019
	Details of fee submitted	(Rs. 100,000/- Dated 02-09-2019)
	The proposed proprietary name / brand name	Paclitaxel 6mg/ml concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 50ml contains: Paclitaxel……300mg
	Pharmaceutical form of applied drug	Concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion (UK)
	For generic drugs (me-too status)	DRIFEN 300MG INJECTABLE SOLUTION M/s Haji Medicine
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted Pharmaceutical equivalence with innovator product Taxol.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) of 3 batches.
Evaluation by PEC:		
Decision: Deferred for clarification regarding storage conditions for of stability study data of finished product which is not as per Zone IVA.		
2597.	Name, address of Applicant / Importer	M/s Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi.
	Details of Drug Sale License of importer	Drug License by the way of Wholesale License No: 0865 Address: Ahsan Pharma Room no.2 Delhi Muslim Building Aram Bagh Road, Karachi. Validity: 16/10/2020
	Name and address of marketing authorization holder (abroad)	M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK.
	Name, address of manufacturer(s)	Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Free sale certificate no. 2017-019 issued by Neijiang Bureau of Ministry of Commerce of the people's republic of China on 27/07/2017. Eudra GMDP status checked from web dated 10-07-2019 show that competent authority of the UK

		confirms the following manufacturer M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China has been inspected dated 21/08/2017, it is considered that it complies with the principle and guideline of GMP laid down in Directive 2003/EC.
	Details of letter of authorization / sole agency agreement	Copy of Exclusive Distributionship Agreement is submitted. M/s Seacross Pharmaceuticals Co., Ltd., Stanmore Bussiness & Innovation Centre, Stanmore Place Howard Road, Stanmore London HA7 1BT, UK. authorizes M/s Ahsan Pharma, Zeenat Medicine Market, A-5, First Floor, Napier Road, Karachi for marketing and selling the the Seacross' products including the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 3687 Dated 16-04-2019
	Details of fee submitted	Rs. 100,000/- Dated 16-04-2019
	The proposed proprietary name / brand name	Azacitidine Seacross powder for suspension for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Azacitidine……..100mg
	Pharmaceutical form of applied drug	Powder for suspension for injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's 30ml glass Vial
	Proposed unit price	Price as per SRO
	The status in reference regulatory authorities	VIDAZA of Baxter Oncology GmbH 33790 Halle/Westfalen Germany
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Chongqing Taihao Pharmaceutical Co., Ltd. No.105, Chuangye Road, Erlang, Jiulongpo District, Chongqing, P. R. China 400039

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies (25ºC±2ºC 60%±5% RH) 24 months and Accelerated study (40ºC±2ºC 75%±5% RH) 6 months of 3 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is submitted against the innovator product VIDAZA® by M/s Colgene. As the product is intended to be administered Sc, therefore In-vitro dissolution testing at 37ºC against the innovator product is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I glass vial
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies (30ºC±2ºC 65%±5% RH) 36 months and Accelerated study (40ºC±2ºC 75%±5% RH) 6 months of 3 batches.
Evaluation by PEC: FSC issuing authority Neijiang Bureau of Ministry of Commerce of the people's republic of China which is not concern regulatory authority i.e. China Food & Drug Administration.		
Decision: Deferred for issuance of CoPP from relevant regulatory authority.		

2598.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor *the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China

	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• **Original Legalized CoPP (Certificate#. 2018-0070)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22424 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 50mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..50mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 50 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan
	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 50MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25°C for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: Submitted comparative dissolution profile of applied Neolymin 50mg Soft Gelatin Capsule with Neoral 25mg, Justify. (The firm has stated that the formulation of cyclosporine capsule 25mg and 50mg is proportional and the manufacturing process is the same.)		
Decision: The Board deferred the case for submission of comparative dissolution profile of the applied product against the reference product of the same strength that is 50mg.		
2599.	Name, address of Applicant / Importer	**M/s** Genome Pharma House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Details of Drug Sale License of importer	**License No:** 0011000 0002403 **Address:** Genome Pharma Hpouse no. 166-A, streetno. 09. Chaklala Scheme III, District Rawalpindi. **Validity: ***28-Aug-2020. **Status:** License to sell drugs as distributor *the firm has submitted the receipt for renewal of DSL dated 25/08/2020.
	Name and address of marketing authorization holder (abroad)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name, address of manufacturer(s)	M/s Anshi Pharmaceutical (Zhongshan) Inc National Health Technology Park, Zhongshan, Guangdong Province China
	Name of exporting country	China

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Original Legalized CoPP (Certificate#. 2018-0069)** stamp and dated on 29-03-2018 by Guangdong Province Food and Drug Administration, People's Republic of China declaring the free sale of applied product and GMP compliant status of the manufacturer..
	Details of letter of authorization / sole agency agreement	Copy of Product specific sole agency agreement is submitted. M/s Anshi Pharmaceuticals authorizes M/s Genome Pharma.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 22423 Dated 30-10-2019
	Details of fee submitted	PKR: 100,000/- dated 30-10-2019
	The proposed proprietary name / brand name	Neolymin 25mg Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule contains: Cyclosporin……..25mg
	Pharmaceutical form of applied drug	Soft gelatin capsule
	Pharmacotherapeutic Group of (API)	ATC Code: L04AD01 IMMUNOSUPPRESSANTS, Calcineurin inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	50's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Capimune 25 mg, Soft capsules of M/s Generics [UK] Limited t/a Mylan
	For generic drugs (me-too status)	SIGMASPORIN MICRORAL 25MG SOFT GELATIN CAPSULE M/s UNIVERSAL ENTERPRISES
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Zhejiang Ruibang Laboratories No. 578, Binhai Ten Road, Economic and Technical Development Zone, Wenzhou, Zhejiang 325025, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for 03 batches (real time at 25^{o}C for 2 years and accelerated for 6 months).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Evaluation by PEC-I: The seal of the submitted CoPP is not intact.		
Decision: Approved as per Import Policy for finished drugs. Firm will submit valid CoPP for further processing of case.		
2600.	Name, address of Applicant / Importer	**M/s** M/s OBS Pakistan Pvt. Ltd., C-14, Manghopir Road, S.I.T.E. Karachi
	Details of Drug Sale License of importer	**License No:** 0950 **Address:** OBS Pakistan PVt LTD Plot No. C-14, Manghopir Road Site area Karachi. **Validity**26-03-2021 **Status:** Drug License by Way of Wholesale
	Name and address of marketing authorization holder (abroad)	**Product License Holder:** Merck Sharp and Dome B.V., Waarderwg 39, 2031 BN Haarlem, the Netherlands.
	Name, address of manufacturer(s)	**Manufactured by**: Steri Pharma, LLC 429S.West street Syracuse, NY 13202, USA **Released By:** Laboratoires Merck Sharp & Dohme Chibret, Route de Marsat-Riom, 63963 Clermont Ferrand Cedex 9, France
	Name of exporting country	Netherland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2FM2-4328) by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer. Certificate Expiration Date: June 24, 2021.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted. MSD authorizes M/s OBS Pakistan.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 21535 Dated 22-10-2019
	Details of fee submitted	(Rs. 100,000/- Dated 22-10-2019)
	The proposed proprietary name / brand name	Zerbaxa, Powder for concentrate for solution for infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftolozane …1gm (eq. to 1.147g of ceftolozane sulfate) Tazobactam… 0.5g (eq. to 0.537g of tazobactam sodium)
	Pharmaceutical form of applied drug	Powder for concentrate for solution for injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	In-house
	Proposed Pack size	10's vials
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Could not be confirmed
	Module-II (Quality Overall Summary)	Submitted.
	Name, address of drug substance manufacturer	M/s Ceftolozane: M/s Acs Dobfar, S.p.A (ACSD4) via Marzabotto, 1,7/9 20871 vimercate (MB) Italy. Tazobactam sodium: M/s Qilu Tianhe Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, 250105 Jinan, Shandong Province, P.R. of China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including

		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data (24 months) at 5±3^{0}C and 6 months at 25^{0}C±60%RH for three batches.
Remarks of Evaluator-I: QOS of module 2 is complete but not as per WHO/Form-5F format. The firm has submitted that the name of legal entity of drug substance manufacturer (Tazobactam Sodium) has been changed from "Qilu Tianhe Pharmacetuical Co., Ltd. to "Shandong Anxin Pharmacetuical Co., Ltd. The firm has stated that the manufacturing site is not changed.Valid GMP of the manufacturer mentioning the changed name and address along with the old name and address of the API manufacturer (certificate no. IT/E/API/04/2020, issued on the basis of inspection conducted on 18-09-2019) is submitted along with the reply. Moreover, updated relevant section (2.3.s.2.1) is submitted as well. Name and address: M/s Shandong Anxin Pharmaceutical Co., Ltd (formerly Qilu Tianhe Pharmaceutical Co., Ltd) No. 10678 Wenliang Road, Dongja town, Licheng District (former No. 849 Dongja town, lichen District, Jinan Shandong, 250105, China.		
Decision: Deferred for submission of complete S part of module 2 and 3 of CTD.		
2601.	Name, address of Applicant / Importer	**M/s** Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi
	Details of Drug Sale License of importer	**Address:** Timax Life Scineces Pvt. Ltd. M-1, Fl-37, Block-B, Gulshan e Jamal Karachi **Validity:** 05/03/2021
	Name and address of marketing authorization holder (abroad)	M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570 Tandogan-ANKARA/ TURKEY
	Name, address of manufacturer(s)	M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Original Legalized CoPP (Certificate#. 2018/2468) issued on 28-06-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No: 20 Kurtkoy-Pendik/ Istanbul-Turkey valid until 28/06/2020.
	Details of letter of authorization / sole agency agreement	Original legalized Authorization letter from Product License Holder: M/s Biem Ilac San. Ve Tic. A.S Turgut Reis Cad. No: 21 06570

		Tandogan-ANKARA/ TURKEY in the name of importer M/s Timax Life Sciences Pvt. Ltd. Mezzanine-1, FL-37, Block-B, Gulshan-e-Jamal Karachi for product MRSACIN-50mg containing lyophilized powder for IV infusion is submitted
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 42062 Dated 07-12-2018
	Details of fee submitted	(Rs. 100,000/- Dated 07-12-201)
	The proposed proprietary name / brand name	MRSACIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Lyophilized tigecycline…..50mg
	Pharmaceutical form of applied drug	Lyophilized powder for solution for IV infusion
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil 50 mg powder for solution for infusion (Belgium)
	For generic drugs (me-too status)	Tygatec 50mg Injection of M/s Safe Pharmaceuticals (Pvt) Ltd. Karachi
	Module-II (Quality Overall Summary)	submitted
	Name, address of drug substance manufacturer	M/s UNIMARK REMEDIES LIMITED 501, 5th Floor, E-Wing, Sky Park CHS Ltd., MMRDA District Centre, Oshiwara Garden Road, Off. S.V. Road, Goregaon (West) Mumbai India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted real time stability study data 25°C±2 and 60%±5 for 2 years and

		accelerated at 40°C±2 and 75%±5.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials etc.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The data is submitted against the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Submitted.
	Stability study data of drug product, shelf life and storage conditions	The firm has submitted real time stability study data 25°C±2 and 60%±5.
Remarks of Evaluator-I: Stability study data (Real time + Accelerated) according to the conditions of Zone-IVA required.		
Decision: Deferred for submission of real time and accelerated stability data of 03 batches according to the conditions of zone IV-A.		

Case no.6: Deferred cases (import) submitted on Form 5F
2602. Nab-Xelpac Injection (Lyophilized Powder) applied by M/s Himmel Pharmaceuticals (Pvt.) Ltd Lahore

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 26966 Dated 13-12-2019 PKR: 50,000/- dated 19-03-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2	Name, address and contact details of Manufacturing site. Product License Holder & Manufacturer: M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** License to Sell drugs as a Distributor No: 0011000 0001520 valid upto 06-Feb-2020
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug.

		Nanoparticle Albumin bound Paclitaxel USP
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Nanoparticle Albumin bound Paclitaxel USP …..100mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Nab-Xelpac Injection (Lyophilized Powder)
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Antineoplastic agents
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration IV
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price ONCOTAXEL 100MG INJECTION of M/S. PHARMEVO (PRIVATE) LIMITED,
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Abraxane 5 mg/ml powder for suspension for infusion (Netherlands)
	1.5.10	Dosage form of applied drug Injection (Lyophilized Powder) : 100mg
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant.

		Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. DA/6-110/2016/3677)** issued on 18-02-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited. • Copy of Product specific sole agency agreement is submitted.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted

2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5	REFERENCE STANDARDS Submitted	
3.2.S.6	CONTAINER CLOSURE SYSTEMS Submitted	
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted

	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 65±5%RH and 6 months at 40^{0}C±75%RH.
Decision of 293rd meeting: Deferred for submission of all commitments of module 1. Evaluation by PEC: The firm has submitted all the commitments of module I. **Decision: Approved as per Policy for inspection of Manufacturer abroad.**		

Deferred cases of COVID-19

Sr. No.	Applicant	Brand name	Composition	Dy No./fee/ date/ form	Pack size and price	GMP status	**Previous decision**
2603.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan Contract	Ajicin 200mg/ 5ml for Suspension	Each 5ml reconstituted Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin…200mg	Dy.No. 12453 dated 03/06/2020Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	M/s Novamed: 22-1-2019 Good level of compliance with GMP.	**Deferred in 295th meeting for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has**

	manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur e road Lahore						**own facility of manufacturing**

Submission by the firm:
The firm has submitted the following;

- Original contract agreement with M/s Novamed Pharma.
- No products are being manufactured on contract basis for M/s Cunningham Pharma.
- Copy of GMP certificate dated 19/04/2019 issue don the basis of inspection conducted on 01/04/2019.
- M/s Cunningham pharma has 7 approved sections.
- The firm does not have the relevant section.

Decision: Approved with USP specifications.

2604.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	Citaquine DS Tablet	Each Film Coated Tablet contains: Chloroquine phosphate……..500mg	Dy.No. 9126 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	30,000/- fee alongwith Fom-5D is required.	**Deferred in 295th meeting for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**

Submission by the firm:
The firm has submitted Form 5D and Differential fee of Rs. 30,000/- vide challan number 0792484 dated 09/06/2020.

GMP inspection dated 13-11-2019 shows that the firm was allowed resumption of production activities in all sections except Sterile Liquid Section of the firm M.s Harmann Laboratories Lahore in as per recommendation of panel inspection report dated 09-10-2019 in following sections.

a- Sterile Section-I (General Injection)
b- Sterile Section-III (Hormonal Injection).

Decision: Approved with USP specifications.

2605.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Lopvir 200mg/ 50mg Tablet	Each Tablet Contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 9318 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5D	As per SRO	GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **submission of requisite fee for revision of formulation as per the reference product.**

Submission by the firm:
The firm has submitted;

- Fee of Rs, 5,000/- vide challan number 2039502 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following;

Each film coated tablet contains:
Lopinavir…..200mg
Ritonavir…...50mg

- No product is being manufactured for M/s CSH Pharma on contract basis.
- Inspection report dated 04/05/2020, satisfactory level of GMP compliance.
- The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012.

Decision: Approved with USP specifications.

2606.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Hydroxy Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9315 dated 29/04/2020Rs. 50,000/- dated 29-04-2020 Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Deferred in 295th meeting for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **Submission of requisite fee for revision of formulation as per the reference product.**

Submission by the firm:
The firm has submitted;

- Fee of Rs, 5,000/- vide challan number 2039501 dated 09/06/2020 for revision of formulation from uncoated to film coated as per the reference product. The correct label claim is given in the following;
  Each film coated tablet contains:
  Hydroxychloroquine sulfate…200mg
- No product is being manufactured for M/s CSH Pharma on contract basis.
- Inspection report dated 04/05/2020, satisfactory level of GMP compliance.
- The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012.

Decision: Approved with USP specifications.

2607.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore **Mfg by:** Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore	Ostar 75mg Capsule	Each capsule contains: Oseltamivir as phosphate …….75 mg	Dy.No. 9316 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore	**Registration Board referred in 295th meeting the case to QA & LT Division to conduct GMP inspection of Firm on priority.**

Submission by the firm:
The firm has submitted;

- No product is being manufactured for M/s CSH Pharma on contract basis.
- Inspection report dated 04/05/2020, satisfactory level of GMP compliance.
- The firm has 3 approved sections (letter No.F.1-100/2005-Lic(Vol-I) dated 1st Aug, 2012.

Decision: Approved with USP specifications.

2608.	Deleted due to duplication						
2609.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Chloquine Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 7779 dated 16/04/2020Rs. 20,000/- dated. 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production Form 5D along with differential fee of Rs. 30,000/- is required..	**Deferred in 295th meeting for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
Submission by the firm: The firm has submitted differential fee of Rs. 30,000/- vide challan number 2025155 dated 06/05/2020 along with Form 5D. **Decision: Approved with USP specifications.**							
2610.	M/s Maple Pharmaceuticals Pvt Ltd Plot No.147, Sector 23, Korangi Industrial Area, Karachi	C-Sure Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7258 dated 14/04/2020Rs. 20,000/- dated 14-04-2020 Form 5		GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 22/12/2020. The firm has applied for plain tablet while it is approved in reference country as chewable	**Deferred in 295th meeting for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**
Submission by the firm: The firm has revised the formulation from Tablet to Chewable tablet as per the reference product along with method of manufacturing, master formula and other relevant documents with the submission of fee of Rs. 20,000/- vide challan number 2001182 dated 18/08/2020. **Decision: Approved with USP specifications.**							
2611.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Macazit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate.….500mg	Dy.No. 11497 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's as per SRO	03/05/2019 inspection dated. The panel recommended renewal of DML.	**Deferred in 295th meeting for submission of method of manufacturing.**
Submission by the firm: The firm has submitted method of manufacturing for the applied product. **Decision: Approved with USP specifications.**							
2612.	M/s Linz Pharmaceuticals Pvt Ltd Plot No 31-G & 31-H,	Azax 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate Eq. to	Dy.No. 11721 dated 21/05/2020Rs. 20,000/- (#1962153)	6's as per SRO	Inspection date 09/01/2020, GMP of the	**Deferred in 295th meeting for updated status of GMP from**

	Sector 15 Korangi Induatrial Area Karachi		Azithromycin……250mg	dated 21-05-2020 Form 5		firm is rated as Good.	**QA & LT.**

Submission by the firm:
The firm has submitted last inspection report dated 09/01/2020, the report concludes that the firm was operating at acceptable level of GMP compliance.
Decision: Approved with USP specifications.

New Applications related to COVID-19 (Import)

2613.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 14513 Dated : 23/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 23/06/2020
	Brand Name +Dosage Form + Strength	Oseltamivir Phosphate Capsule 75mg
	Composition	Each capsule contains: Oseltamivir as Phosphate……75mg
	Finished Product Specification	USP
	Pharmacological Group	antiviral
	Shelf life	18 months
	Pack size & Demanded Price	As per SRO
	International availability	Tamiflu 75mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.
	Me-too status	Tamiflu 75mg capsule by M/s Roche.
	Stability studies	Accelerated stability study data of 03 batches for 6 months Real time stability data of 03 batches for 09months is submitted
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-19-01129 **Certified by:** Food and Drug Administration Ministry of Public health **Date of issuance:** 21/08/2019 **Free sale:** yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	Real time stability data is till 9 months,
	Decision: Deferred for confirmation of shelf life as 9 months stability data has been submitted	
2614.	Name and address of Applicant	M/s Trans-Continental Pharma (pvt) Ltd. 23-B Gul Plaza Charsada Road, KPK Peshawar.
	Detail of Drug Sale License	License to sell drugs as Distributor

		Name: Trans-Continental Pharma (pvt) Ltd, Office No. 13-14-B, Gul Plaa Charsada Road Peshawar. Validity: 18/11/2021 No. 736WSL
	Product License Holder & Manufacturer	Manufacturer: M/s The Government Pharmaceutical Organization, 138 Moo 4, Rangsit-Nakhonnayok Rd., Thanyaburi, Pathumthani 12110, Thailand. MAH:
	Name of exporting country	Thailand
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 13657 Dated : 15/06/2020
	Fee including differential fee	Rs : 100,000 Dated : 15/06/2020
	Brand Name +Dosage Form + Strength	Lopinavir/Ritonavir Tablet 200/50mg
	Composition	Each film coated tablet contains: Lopinavir……200mg Ritonavir…….50mg
	Finished Product Specification	USP
	Pharmacological Group	Anti retroviral
	Shelf life	2 years
	Pack size & Demanded Price	Rs. 15,500/- per 120 tablets
	International availability	Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved.
	Me-too status	Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED, Rweg No. 62250
	Stability studies	Accelerated stability study data of 03 bathes for 6 months Real time stability data of 03 batches for 24 months is submitted as per Zone IVA
	Detail of certificates attached	**Medicinal product certificate** **Certificate No**: 1-2-03-03-20-00304 **Certified by:** Food and Drug Administrtaion Ministry of Public health **Date of issuance:** 23/04/2020 **Free sale:** Yes **GMP status:** Copy of GMP certificate No. 1-2-07017-20-00007 isuued by Food and Drug Administration, Ministry of public health is attached.
	Remarks of the Evaluator.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

Case no. 01 Review of the previously presented cases

Following application was approved in 286th meeting of Registration Board held on 14th - 16th November, 2018. During subsequent processing of the said case, it has been identified that the evidence of approval of applied formulation i.e., "Each capsule contain Gabapentin …. 60mg" is not verifiable from any of the reference regulatory authorities, rather "Gabapentin 600mg tablet" is approved by US FDA. Hence the case is presented before the Board for re-consideration.

2223	**Name and address of manufacturer / Applicant**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Brand Name +Dosage Form + Strength	Parkopentin 600mg Capsule
	Composition	Each Capsule Contains: Gabapentin…600mg

	Diary No. Date of R& I & fee	Dy.No 24892 dated 18-07-2018 Rs.20,000/- Dated 16-07-2018
	Pharmacological Group	Anti-convulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per Drap Policy
	Approval status of product in Reference Regulatory Authorities.	**USFDA Approved**
	Me-too status	**Kendis Tablets 600mg Reg # 064838**
	GMP status	The CLB in its 259th meeting held on 29th and 30th March 2018 has considered and approved the grant of DML by way of formulation. g) Tablet (General Section) h) Capsule (General Section) i) Liquid Syrup (General Section)
	Remarks of Evaluator	
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	

Case no. 02 Registration applications for local manufacturing of (Human) drugs

c. New cases

2224.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Merolit 1gm Injection
	Composition	"Each vial contains: Meropenem……1gm"
	Diary No. Date of R& I & fee	Dy. No 16389 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator[II]	Initially form has submitted stability study reports for accelerated conditions but now the applicant has requested a sunder: "This is our product Merolit 500mg & 1gm, its me too status is available, we want to withdraw its stability and require normal approval of product."
	Decision: Deferred for consideration as per queue.	
2225.	**Name and address of manufacturer / Applicant**	**"M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad** Contract manufacturing by **M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad"**
	Brand Name + Dosage Form + Strength	Merolit 500mg Injection
	Composition	"Each vial contains:

		Meropenem…500mg"
	Diary No. Date of R& I & fee	Dy. No 16390 dated 07-03-2019 Rs50,000/- Dated 07-03-2019
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [II]	
	Decision: Deferred for consideration as per queue.	

b. Deferred cases

2226.	**Name and address of manufacturer / Applicant**	**M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name +Dosage Form + Strength	Zibix 200mg Tablet
	Composition	Each film coated Tablet Contains: Celecoxib……200mg
	Diary No. Date of R& I & fee	Dy.No.16179 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength/dosage form)	Coxia 200 mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Celebrex 200mg capsule" of M/s Upjohn UK Limited approved by MHRA of UK whereas applied formulation is of tablet dosage form. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2227.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 10mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…10mg Atorvastatin (as calcium trihydrate) …10mg"

	Diary No. Date of R& I & fee	Dy. No 28143 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Combitrol 10/10 tablet by M/s Ferozsons Labs. (Reg#050815)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (M-291)	Deferred for confirmation of valid DML status of the firm from Licensing Division.
	Firm's response	Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	
2228.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Zorfix 5mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…5mg Atorvastatin (as calcium trihydrate) ……10mg"
	Diary No. Date of R& I & fee	Dy. No 28142 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Atease 5+10mg Tablet by M/s PharmEvo (Reg#050559)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Previous decision (291):	Deferred for the following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Confirmation of DML status.
	Firm's response	• Following reference has been verified: "Caduet tablet" of M/s PHARMACIA approved by US FDA. • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued.
	Decision: Approved with innovator's specification.	
2229.	Name and address of manufacturer / Applicant	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg"

	Diary No. Date of R& I & fee	Dy. No 771 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	070493 Prefair 500/15mg M/s Merck, Balochistan
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.
	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…500mg
	Decision: Approved.	
2230.	**Name and address of manufacturer / Applicant**	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Litamet 15/850 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg"
	Diary No. Date of R& I & fee	Dy.No 772 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	076217 Muppet 15mg/850mg Tablet M/s PPP, Karachi.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Previous decision (295):	Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.

	Firm's response	Firm has submitted revised master formulation in line with the reference product i.e., Each Film Coated Tablet Contains: Pioglitazone as HCl…15mg Metformin HCl…850mg
	Decision: Approved.	
2231	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name+Dosage Form + Strength	Azimed 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 44138 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azithromycin 250mg Capsules Unipharma (Pvt) Ltd., 071421
	GMP status	28-09-2017 and good
	Remarks of the Evaluator XIII	• Azithromycin "as" dihydrate is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Previous Decision (M-295)	Deferred for evidence of approval of relevant/required manufacturing facility and revision of formulation as per the innovator / reference product along with submission of fee for revision of formulation.
	Firm's response	• Firm has submitted revised master formulation in line with the reference product i.e., "Each Capsule Contains: Azithromycin as dihydrate……250mg" • Firm has submitted copy of letter from Secretary CLB dated 14-02-2020, wherein Renewal of DML w.e.f 05-10-2017 has been issued including the section of "Capsule (general)".
	Decision: Approved as per following composition: **"Each Capsule Contains:** **Azithromycin as dihydrate……250mg"**	
2232.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 100mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate……6mcg Budesonide……100mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 100/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 100mcg + 6mcg capsule of M/s Highnoon

	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting **(M-289)**. Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1).
	Previous decision (M-295):	Registration Board deferred the case for further deliberation

		in the light of decision of 290th meeting of Registration Board.
2233.	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Brethease 200mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….200mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective beta$_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications (M-243): • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting (M-289). Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of

		Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1)
	Previous decision (295):	Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.
	Firm's response: • As concerned of manufacturing controls for particle size of blend, we will use DPI grade API & lactose (Respitose) as an excepient. Therefore, we do not require spiral jet mill/high shear mixer to fine the material. We have arranged micronized Budesonide, formoterol fumarate and inhalation grade lactose (Respitose SV003) in our proposed formulation. • We are also providing our commitment/undertaking for arrangement/purchase of Spiral Jet Mill/high shear mixer, when our applied products have requirements of particle size reduction in future. • We have separate manufacturing facility for capsules (General) & capsules (steroidal). Our Steroidal capsule manufacturing section is also verified by DRAP Officials during their inspections. We also have separate dispensing booth for dispensing of steroidal API. • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly, we have also included "target delivery dose" in our product specifications.	
	Decision: Registration Board deliberated upon submission of firm and decided as under: **ix. Approved the applied product considering the fact that the use of micronized DPI grade APIs does not necessitate the use of Spiral Jet Mill/high shear mixer.** **x. The firm shall include the test of Aerodynamic particle size distribution" in the finished product specifications to ensure the required particle size of the formulation blend.** **xi. Firm shall use micronized DPI grade excipient for the applied product.** **xii. Registration letter shall be issued with following label claim:** **"Each capsule contains:** **Formoterol Fumarate (micronized) ……. 6mcg** **Budesonide (micronized) ……..… 200mcg"**	
2234.	Name and address of manufacturer / Applicant	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 120 injection
	Composition	Each vial contains: Artesunate ……. 120mg

	Diary No. Date of R& I & fee	Dy. No. 1115, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076073)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2235.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 30 injection
	Composition	Each vial contains: Artesunate ……. 30mg
	Diary No. Date of R& I & fee	Dy. No. 1118, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076072)
	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2236.	**Name and address of manufacturer / Applicant**	**M/s Surge Laboratories Pvt Ltd, 10-Km Fasisalabad Road, Bhikhi, Distt. Sheikhupura.**
	Brand Name +Dosage Form + Strength	Rotem-AT 60 injection
	Composition	Each vial contains: Artesunate ……. 60 mg
	Diary No. Date of R& I & fee	Dy. No. 1117, 02-05-2017, Rs. 20,000/- (02-05-2017)
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	1's & 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma (Pvt) Ltd. Karachi (Reg#057719)

	GMP status	Last inspection report dated 09-11-2017.
	Previous Remarks of the Evaluator.	Firm does not have Dry powder Injection (General) section.
	Previous Decision (M-282)	Deferred for evidence of approval of required manufacturing facility i.e. "Dry powder Injection (general)" or Lyophilizer
	Firm's response	Firm has submitted section approval letter for "Sterile Dry Powder Injectable (General).
	Evaluation by PEC	Firm did not have section approval at the time of submission of application i.e., 02-05-2017.
	Decision of 296th meeting: Approved.	
2237.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy. No 28456 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Previous Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019. • Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2238.	**Name and address of manufacturer / Applicant**	**"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"**
	Brand Name +Dosage Form + Strength	Newgaba 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy. No 28455 dated 20-08-2018 Rs.20,000/- Dated 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsule by M/s Getz Pharma (Reg#048725)

	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019 concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-292)	Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 23-04-2019. • Finished product specifications have also been submitted.
	Decision of 296th meeting: Approved.	
2239.	**Name and address of manufacturer / Applicant**	**M/s. HiMedic Pharmaceutcals (Pvt) Ltd.0 Lahore**
	Brand Name +Dosage Form + Strength	Soclar Drops 50mg/ml
	Composition	Each ml Contains: Cefaclor (as monohydrate)……50mg
	Diary No. Date of R& I & fee	Dy. No.31; 26-07-2016; Rs.20,000/- (26-07-2016)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15ml; Rs. 131.66/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA as suspension dosage form
	Me-too status (with strength and dosage form)	Slate Drops 50mg/ml of M/s SAMI Pharmaceuticals (Reg.# 075939)
	GMP status	Last GMP inspection conducted on 09-08-2018
	Previous Remarks of the Evaluator[II]	
	Previous Decision (M-285)	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Firm's response	• Firm has submitted copy of GMP certificate issued on the base of inspection conducted on 24-01-2020.
	Decision of 296th meeting: Approved with USP specifications.	
2240.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, Pakistan by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 2.25g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…2.0g Tazobactam sodium eq to Tazobactam…0.25g"
	Diary No. Date of R& I & fee	Dy.No 7048 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.

	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044142; Tazobact 2.25g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	
2241.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 4.5g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…4.0g Tazobactam sodium eq to Tazobactam…0.5g"
	Diary No. Date of R& I & fee	Dy.No 7049 dated 19-02-2019 Rs.50,000/- 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044143 Tazobact 4.5g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Previous decision (M-295)	Deferred for the following: • Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submit contract manufacturing agreement between applicant and manufacturer.
	Firm's response	• Firm has submitted they have been granted registration of 11 products by contract manufacturing against their 4 sections. • Copy of contract agreement has also been submitted.
	Decision: Approved.	

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. Deferred Cases

2242.	**Name and address of Applicant**	**M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan**
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • Only brand name has been mentioned without label claim. • The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis.

		• Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA. • The firm submitted Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 26.09.2019.
	Previous decision	The Board in its 293rd meeting deferred the case for or changing the address of applicant in Form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Previous decision (M-295)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Remarks of Evaluator	Following reference of me-too product has been verified: "DOXYSIN WATER SOLUBLE POWDER" of M/s UNIVET PHARMACEUTICALS, RAWALPINDI. (Reg.#033256)
	Decision of 296th meeting: Approved.	

Case no. 04 Registration applications of newly granted DML or New section (Human)

c. New DML /section

M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa, has been granted approval for two new tablet sections in 274th meeting of CLB. Now the firm has applied following products for priority consideration against these two new sections.

2243.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15180: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…5mg"

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)
	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 5mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China		
API Lot No.	ETG20190101		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-001	ERTab-001	ERTab-001
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:		
13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

2244.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15181: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia 15mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04)
	Reference to Finished product specifications	Inovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglatro 15mg tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China.		
API Lot No.	ETG20190101		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-004	ERTab-005	ERTab-006

Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
9.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard.

		• Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
10.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		P - PART
11.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
12.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Registration Board deferred the applications of Ertuvia 5mg Tablet & Ertuvia 15mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
9.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
10.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for

		Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
	P - PART	
11.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
12.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

2245.		
	Name, address of Applicant / Marketing Authorization Holder	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15183: 29-06-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia-S 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…….5mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin……100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--

	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China		
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-007	ERTab-008	ERTab-009
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report:

		✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
15.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]:		

2246.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"**
	Name, address of Manufacturing site.	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15182: 29-06-2020

	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**Ertuvia-S 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…100mg"
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic (A10BK04) , (A10BD24)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglujan approved by USFDA
	For generic drugs (me-too status)	--
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 25-01-2019.
	Name and address of API manufacturer.	M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies against the innovator product "Steglujan tablets" in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin L-Pyroglutamic Acid:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China. **Sitagliptin Phosphate Monohydrate:** M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China
API Lot No.	Ertugliflozin L-Pyroglutamic Acid: ETG20190101 Sitagliptin Phosphate Monohydrate: 1827-0001-18079
Description of Pack (Container closure	Alu-Alu blister in unit carton

system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2, 3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	ERTab-010	ERTab-011	ERTab-012
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	05-2019	05-2019	05-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data of applied products and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting:

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empagen tablet 10mg & 25mg", which was conducted on 25-10-2019, and was presented in 294th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Firm has demonstrated audit trail reports of testing. ✓ The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic Acid:** Copy of GMP certificate (JS20180935) issued by the Jiangsu Drug Administration in the name of Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China has been submitted which is valid upto 26-11-2023. **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of Drug Manufacturing License (No. ZHE20020015) for M/s Zhejiang Yongtai Pharmaceutical Co., Ltd. No.1, 4th Donghai Road, Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China, issued by Zheijiang Food & Drug Administration
15.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic Acid:** Firm has submitted copy of Form issued by ADC DRAP Peshawar office dated 26-02-2019 specifying import 189gm Ertugliflozin L-pyroglutamic acid from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou City, Jiangsu Province 213105, China **Sitagliptin Phosphate Monohydrate:** Firm has submitted copy of commercial invoice attested by ADC, DRAP Karachi, dated 02-01-2019 for the import of 350 Kg of Sitagliptin phosphate monohydrate.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
11.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
12.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
13.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
		P - PART
14.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP

		chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
15.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Decision: Decision: Registration Board deferred the applications of Ertuvia-S 5/100 mg Tablet & Ertuvia-S 15/100 mg Tablet for the following deficiencies:

Sr. No.	Section #.	Deficiencies
		Ertugliflozin-LPGA
11.	***3.2.S.4***	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities. Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.
12.	***3.2.S.5***	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted.
		Sitagliptin Phosphate
13.	***3.2.S.4***	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required. • Acceptance criteria for the parameter of Accuracy in "Analytical Method Verification" studies has been declared in terms of "RSD should not be more than $\pm$2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation. • Analytical record for the batch analysis of Drug substance, performed by the Drug product manufacturer shall be submitted.

P - PART		
14.	***3.2.P.5.5***	• Acceptance criteria for the parameter of Accuracy in "Analytical Method Validation" studies has been declared in terms of "RSD should not be more than ±2%", instead of the "percentage recovery". Justification shall be submitted in this regard. • Specificity parameter has been performed by injecting the mobile phase as a blank, placebo, sample and reference solution. Whereas USP chapter <1225> & ICH Q2 (R1) guidelines suggests spiking the drug substance with appropriate levels of impurities or exposing the drug product sample to relevant stress conditions (e.g., light, humidity, acid or base hydrolysis, oxidation). Justification shall be submitted for this variation in method.
15.	***3.2.P.8***	• Calculation of Assay results during stability studies has been performed by using the "theoretical concentration" of the sample solution instead of the actual concentration based upon the weight of the drug product sample used to prepare the sample solution. Justification shall be submitted in this regard.

Case no. 05 Registration applications of import cases

a. New Cases (Veterinary)

2247	**Name and address of Applicant**	**M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan**
	Detail of Drug Sale License	Address: **M/s Prix Pharmaceutica,** 26 abbot road Lahore (Godown: Plot NO. 5, Pharmacity, 30Km Multan Road Lahore. Validity: 12/06/2022`
	Name and address of manufacturer	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name and address of marketing authorization holder	M/s Fatro S.P.A, Via Emilia, 285-40064, Ozzano Emilia (Bo) Italy.
	Name of exporting country	**Italy**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 75 Dated 14-07-2015
	Fee including differential fee	Rs. 50,000/- Dated 10-07-2015
	Brand Name +Dosage Form + Strength	**ZOOCOLAGOGO C.M. Oral Powder**
	Composition	Each 18gm sachet contains: Rhubarb ……. 9gm Boldo leaf …….. 6gm Condurango ……. 2gm Nux vomica ……. 1gm
	Finished Product Specification	Manufacturer's specification
	Pharmacological Group	Products for alimentary tract and metabolism
	Shelf life	5 years
	Demanded Price	Decontrolled
	Pack size	1's
	International availability	Approved by Italy (Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products)
	Me-too status	N/A
	Stability studies	Firm has submitted long term (60 months) at 25+2°C, 60+5%RH & accelerated (06 months) stability data at 40+ 2°C, 75+ 5% RH for three batches.

	Detail of certificates attached	• **Original Legalized CoPP** **Certificate No:** 163/2018/C **Certifying Authority:** Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products **Issue Date:** 19-08-2018 **Free sale in exporting country: Yes** • **GMP of manufacturer:** Yes **GMP Certificate** The GMP certificate (No. NBF/18/2017/V) issued by Ministry of Health - General Directorate of Animal Health and Veterinary Drugs Italy, submitted by the firm and also available at EUDRA GMP database, valid upto 23-02-2020. **Sole Agency Agreement:** Firm has submitted declaration form M/s Fatro S.P.A, Italy wherein M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan has been declared as sole agent in Pakistan for their product "Zoocolagogo C.M. oral powder".
	Remarks of the Evaluator:	
	Decision: Registration Board deferred the case for following: **vii. Opinion from H&OTC division regarding the classification of applied formulation.** **viii. Submission of stability data of the applied product as per Zone IV-a conditions.** **ix. Submission of valid legalized GMP certificate of the finished product manufacturer.**	

Case no. 06 Registration applications of drugs for which stability study data is submitted

e. New cases

2248.	**Name and address of manufacturer / Applicant**	**M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	Jenta 80mg Injection
	Composition	Each ampoule contains: Gentamicin as sulphate ……. 80mg
	Diary No. Date of R& I & fee	Dy.No.728, 27-7-2016, Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	2 ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL GENTAMICIN 80mg/2mL Injection BP (TGA)
	Me-too status	GENXAT of Surge pharma
		Last GMP Inspection dated 03-04-2019 with conclusive remarks of acceptable cGMP compliance.
	Remarks of Evaluator	
	Decision:	

STABILITY STUDY DATA	
Drug	Jenta 80mg Injection
Name of Manufacturer	M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.
Manufacturer of API	M/s Fujian Fukang Pharmaceutical Co., Ltd., Jiangyin Industrial Estate, Fujian, China
API Lot No.	FG 1608226
Description of Pack	LDPE Ampoule

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,1,3,6 months		
Batch No.	001	002	003
Batch Size	20,000 ampoules	20,000 ampoules	20,000 ampoules
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	20-01-2017	20-01-2017	20-01-2017
No. of Batches	03		
Date of Submission	03-12-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
15.	COA of API	Yes
16.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate (Certificate#FJ20170003) issued by Germany, **valid upto 09-04-2022**
	Protocols followed for conduction of stability study and details of tests.	Yes
17.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
18.	Documents confirming import of API etc.	Copy of ADC attested invoice for Gentamicin sulfate, dated 16-12-2016.
19.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
20.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
21.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

vii. Firm has submitted data for Bio-Assay analysis as per USP monograph.

viii. Firm has used LDPE ampoules as primary container closure system for applied formulation which is a semi permeable container. As per ICH guidelines for drug products packaged in semi-permeable containers the testing conditions are:

Study	Storage conditions
Long Term	30°C ± 2°C/35% RH ± 5% RH
Accelerated	40°C ± 2°C/not more than (NMT) 25% RH

ix. The firm has submitted reports of 6 months accelerated & long term stability studies, for all the above three batches of Jenta 80mg injection, the firm has derived water loss rate by applying alternate approach given in the ICH Q1A (R2) guidelines as below:

Batch No.: 001 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3808	0.04	11	3.3821	3.3814	0.06
2	3.3218	3.3208	0.06	12	3.4509	3.4499	0.09
3	3.4285	3.4280	0.03	13	3.4742	3.4737	0.04
4	3.3156	3.3143	0.07	14	3.4351	3.4343	0.07
5	3.3672	3.3661	0.06	15	3.3577	3.3570	0.06
6	3.4264	3.4255	0.05	16	3.4231	3.4222	0.08
7	3.4305	3.4301	0.02	17	3.3688	3.3684	0.04
8	3.3721	3.3706	0.08	18	3.3103	3.3097	0.05
9	3.3985	3.3979	0.03	19	3.3280	3.3277	0.03
10	3.3912	3.3897	0.08	20	3.3902	3.3893	0.08

Batch No.: 001 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3815	3.3790	0.14	11	3.3821	3.3806	0.13
2	3.3218	3.3198	0.11	12	3.4509	3.4496	0.11
3	3.4285	3.4256	0.16	13	3.4742	3.4726	0.14
4	3.3156	3.3134	0.13	14	3.4351	3.4339	0.10
5	3.3672	3.3644	0.16	15	3.3577	3.3563	0.13
6	3.4264	3.4237	0.15	16	3.4231	3.4216	0.13
7	3.4305	3.4277	0.16	17	3.3688	3.3672	0.14
8	3.3721	3.3692	0.16	18	3.3103	3.3084	0.17
9	3.3985	3.3963	0.12	19	3.3280	3.3265	0.14
10	3.3912	3.3892	0.11	20	3.3902	3.3890	0.11

Batch No.: 001 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3815	3.3780	0.20	11	3.3821	3.3796	0.22
2	3.3218	3.3180	0.22	12	3.4509	3.4486	0.20
3	3.4285	3.4246	0.22	13	3.4742	3.4716	0.22
4	3.3156	3.3124	0.18	14	3.4351	3.4329	0.19
5	3.3672	3.3634	0.21	15	3.3577	3.3553	0.21
6	3.4264	3.4227	0.21	16	3.4231	3.4206	0.22
7	3.4305	3.4257	0.27	17	3.3688	3.3662	0.23
8	3.3721	3.3682	0.22	18	3.3103	3.3074	0.26
9	3.3985	3.3953	0.18	19	3.3280	3.3265	0.14
10	3.3912	3.3877	0.20	20	3.3902	3.3880	0.19

Batch No.: 002 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3942	3.3935	0.04	11	3.3924	3.3917	0.06
2	3.3861	3.3851	0.06	12	3.3891	3.3881	0.09
3	3.4025	3.4020	0.03	13	3.3642	3.3637	0.04
4	3.3814	3.3801	0.07	14	3.3904	3.3896	0.07
5	3.3881	3.3870	0.06	15	3.3891	3.3884	0.06
6	3.3790	3.3781	0.05	16	3.3947	3.3938	0.08
7	3.3953	3.3949	0.02	17	3.3982	3.3978	0.04
8	3.3684	3.3669	0.08	18	3.3862	3.3856	0.05
9	3.3943	3.3937	0.03	19	3.3944	3.3941	0.03
10	3.3769	3.3754	0.08	20	3.3983	3.3974	0.08

Batch No.: 002 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3912	3.3887	0.14	11	3.3924	3.3909	0.13
2	3.3704	3.3684	0.11	12	3.3891	3.3878	0.12
3	3.3845	3.3816	0.16	13	3.3642	3.3626	0.14
4	3.3905	3.3883	0.12	14	3.9904	3.9892	0.09
5	3.3887	3.3859	0.16	15	3.3891	3.3877	0.12
6	3.3781	3.3754	0.15	16	3.3947	3.3932	0.13
7	3.3826	3.3798	0.16	17	3.3982	3.3966	0.14
8	3.3942	3.3913	0.16	18	3.3862	3.3843	0.17
9	3.3807	3.3785	0.12	19	3.3944	3.3929	0.13
10	3.3841	3.3821	0.11	20	3.3983	3.3971	0.11

Batch No.: 002 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3912	3.3877	0.20	11	3.3924	3.3899	0.22
2	3.3704	3.3666	0.21	12	3.3891	3.3868	0.20
3	3.3845	3.3806	0.22	13	3.3642	3.3616	0.23
4	3.3905	3.3875	0.17	14	3.9904	3.9882	0.17
5	3.3887	3.3849	0.21	15	3.3891	3.3867	0.21
6	3.3781	3.3744	0.21	16	3.3947	3.3922	0.22
7	3.3826	3.3787	0.22	17	3.3982	3.3956	0.23
8	3.3942	3.3903	0.22	18	3.3862	3.3842	0.18
9	3.3807	3.3775	0.18	19	3.3944	3.3929	0.13
10	3.3841	3.3806	0.20	20	3.3983	3.3961	0.19

Batch No.: 003 Filled Volume: 2 ml 1 Month Completion Date: 06-01-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 1 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3845	0.04	11	3.3874	3.3867	0.06
2	3.3945	3.3935	0.06	12	3.3907	3.3897	0.09
3	3.3793	3.3788	0.03	13	3.3791	3.3786	0.04
4	3.3824	3.3811	0.07	14	3.3953	3.3945	0.07
5	3.3948	3.3937	0.06	15	3.3778	3.3771	0.06
6	3.3887	3.3878	0.05	16	3.3827	3.3818	0.08
7	3.3796	3.3792	0.02	17	3.3809	3.3805	0.04
8	3.3821	3.3806	0.08	18	3.3945	3.3939	0.05
9	3.3943	3.3937	0.03	19	3.3824	3.3821	0.03
10	3.3844	3.3829	0.08	20	3.3798	3.3789	0.08

Batch No.: 003 Filled Volume: 2 ml 3 Month Completion Date: 06-03-2020

No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 3 Month	Weight Difference or Loss of Water (%)
Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
1	3.3852	3.3827	0.14	11	3.3874	3.3859	0.13
2	3.3945	3.3925	0.11	12	3.3907	3.3894	0.12
3	3.3793	3.3764	0.16	13	3.3791	3.3775	0.14
4	3.3824	3.3802	0.12	14	3.3953	3.3941	0.11
5	3.3948	3.3920	0.16	15	3.3778	3.3764	0.12
6	3.3887	3.3860	0.15	16	3.3827	3.3812	0.13
7	3.3796	3.3768	0.16	17	3.3809	3.3793	0.14
8	3.3821	3.3792	0.16	18	3.3945	3.3926	0.17
9	3.3943	3.3921	0.12	19	3.3824	3.3809	0.13
10	3.3844	3.3824	0.11	20	3.3798	3.3786	0.11

Batch No.: 003 Filled Volume: 2 ml 6 Month Completion Date: 05-06-2020

Storage Condition: 30°C & 65% RH				Storage Condition: 40°C & 75% RH			
No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month (gm)	Weight Difference or Loss of Water (%)	No. of Plastic bottle	Initial Weight (gm)	Weight after 6 Month	Weight Difference or Loss of Water (%)
1	3.3852	3.3817	0.20	11	3.3874	3.3849	0.22
2	3.3945	3.3907	0.21	12	3.3907	3.3884	0.20
3	3.3793	3.3754	0.22	13	3.3791	3.3765	0.23
4	3.3824	3.3792	0.18	14	3.3953	3.3931	0.19
5	3.3948	3.3910	0.21	15	3.3778	3.3754	0.21
6	3.3887	3.3850	0.21	16	3.3827	3.3802	0.22
7	3.3796	3.3748	0.27	17	3.3809	3.3783	0.23
8	3.3821	3.3782	0.22	18	3.3945	3.3916	0.26
9	3.3943	3.3911	0.18	19	3.3824	3.3807	0.15
10	3.3844	3.3809	0.20	20	3.3798	3.3776	0.20

Moreover firm has submitted Container Qualification Studies for Low Density Polyethylene (LDPE), as per USP. The submitted studies make following declarations:

- Material pass the test describe in European Pharmacopoeia.
- Material pass the test describe in USP.
- LDPELE6609 PH has FDA drug master file number DMF 17927 (24086 ex Porvoo)
- PCSIR test reports for extractable metals concluded that No Extractable was found in LDPE sample tested as per USP<661.1>.
- Sample analysed as per USP <661.2> and found results within the USP specification.

Decision: Registration Board deliberated the case in detail and considering the submitted stability data "Container qualification studies", the Board decided to approve Jenta 80mg injection (Gentamicin)", of M/s Hudson Pharma Pvt. Ltd. D-93 north western industrial zone, port Qasim, Karachi.

f. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2249.	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Aglizon 10mg Tablet Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…10mg (In-house specifications)	Form-5D Dy. No: 19554 Dated 30.10.2017 Rs.50,000/- As per SRO (1x10's, 2x10's, 3x10's)	FORXIGA dapagliflozin (as propanediol monohydrate) 10 mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA	
Drug	Aglizon 10mg Tablet
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)

Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4341)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
17.	COA of API	Yes
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion		
39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.

<table>
<tr><td>40.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>➢ <u>Declaration by WIS Pharmtec Co. Ltd, China</u>
The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information.
Batch No.: DGF20180101
Mfg Date: 05.01.2018
➢ <u>Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China</u>
Invoice No. WIS180047
Quantity imported: 0.22 Kg
Date of import: 28.03.2018
ADC Attestation Date: 14.05.2018
Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.
Batch No.: DGF20180101</td></tr>
<tr><td>41.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No. The firm submitted that these were in minute quantity and free of cost.</td></tr>
<tr><td>42.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, China for API valid till 18.08.2019, issued by China FDA.</td></tr>
<tr><td>43.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Shangai Pharma Group Changzhou.</td></tr>
<tr><td>44.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of reference standard and impurity A have been submitted.</td></tr>
<tr><td>45.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>46.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of three qualified staff involved in product development. One of them is intermediate passed, who is assistant officer production</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>47.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
i. Development protocol.
j. Stability Study Protocol.</td></tr>
<tr><td>48.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.<table><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr><tr><td>TF001</td><td>05-2018</td><td>1000/992</td></tr><tr><td>TF002</td><td>05-2018</td><td>1000/988</td></tr><tr><td>TF003</td><td>05-2018</td><td>1000/984</td></tr></table></td></tr>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td><table><tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr><tr><td>TF001</td><td>1000</td><td>992</td><td>480</td></tr><tr><td>TF002</td><td>1000</td><td>988</td><td>540</td></tr></table></td></tr>
</table>

		TF003	1000	984	540
QA / QC DATA					
50.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Yes			
51.	Method used for analysis of API along with COA.	The firm has applied supplier's method for analysis of API and has submitted their analytical reports, raw data sheets & relevant chromatograms.			
52.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	• The firm has submitted photocopy of Finished Product specification & Test method. • Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)			
53.	Reports of stability studies of API from manufacturer.	The firm has submitted copies of reports of 06 Months Accelerated and 18 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API. **The firm has also submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API, wherein impurity A has not been tested.**			
54.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.			
55.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation.			
56.	Record of comparative dissolution data.	pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8. **Feature** / **Reference product** Brand name: Forxiga Tab. 10mg Batch No.: NX685 Mfg. date: NIL			
57.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.			

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC: Firm has now submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2250.	M/s Helix Pharma (Pvt.) Ltd.,	Aglizon 5mg Tablet	Form-5D Dy. No: 19540	FORXIGA dapagliflozin (as

	Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700	Each film-coated tablet contains: Dapagliflozin as propapendiol monohydrate…5mg (In-house specifications)	Dated 30.10.2017 Rs.50,000/- (**Duplicate dossier)** As per SRO (1x10's, 2x10's, 3x10's)	propanediol monohydrate) 5mg film coated tablets blister pack. TGA approved. Could not be confirmed The firm was last inspected on 10.08.2017, wherein it was concluded that "Based on the areas inspected, the people met and documents reviewed of M/s Helix Pharmaceuticals Pvt. Ltd Karachi found satisfactory and compliant as per cGMP requirement."

STABILITY STUDY DATA			
Drug	Aglizon 5mg Tablet		
Name of Manufacturer	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700		
Manufacturer of API	Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China.		
API Lot No.	DGF20180101 (MFG DATE: 05.01.2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000	1000	1000
Manufacturing Date	05.2018	05.2018	05.2018
Date of Initiation	26.05.2018	26.05.2018	26.05.2018
No. of Batches	03		
Date of Submission	23.04.2019 (Dy. No. 4342)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
17.	COA of API	Yes
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API	Copy of GMP certificate issued by China Food & Drug Administration, valid upto 18.08.2019.

	manufacturer issued by regulatory authority of country of origin.	
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP Karachi on 14.05.2018, has been submitted.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped signature)
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was conducted on 18.08.2017, and was presented in 273rd meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
40.	Documents for the procurement of API with approval from DRAP (in case of import).	➢ **Declaration by WIS Pharmtec Co. Ltd, China** The firm has imported Dapagliflozin API 0.22 kg from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information. Batch No.: DGF20180101 Mfg Date: 05.01.2018 ➢ **Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China** Invoice No. WIS180047 Quantity imported: 0.22 Kg Date of import: 28.03.2018 ADC Attestation Date: 14.05.2018 Manufacturer: Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, Jiangsu, China. Batch No.: DGF20180101

<table>
<tr><td>41.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Yes</td></tr>
<tr><td>42.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has provided copy of GMP certificate of M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Add: Daixi Street Luyong Town, Wujin District. Changzhou, China for API valid till 18.08.2019, issued by China FDA.</td></tr>
<tr><td>43.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
Copy of Vendor Certification Questionnaire filled for M/s Shangai Pharma Group Changzhou.</td></tr>
<tr><td>44.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of reference standard and impurity A have been submitted.</td></tr>
<tr><td>45.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>46.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of three qualified staff involved in product development. One of them is intermediate passed, who is assistant officer production</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>47.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
k. Development protocol.
l. Stability Study Protocol.</td></tr>
<tr><td>48.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>TF001</td><td>05-2018</td><td>1000/986</td></tr>
<tr><td>TF002</td><td>05-2018</td><td>1000/990</td></tr>
<tr><td>TF003</td><td>05-2018</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>TF001</td><td>1000</td><td>986</td><td>480</td></tr>
<tr><td>TF002</td><td>1000</td><td>990</td><td>570</td></tr>
<tr><td>TF003</td><td>1000</td><td>984</td><td>540</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>The firm has applied supplier’s method for analysis of API and has submitted their analytical reports, raw data sheets & relevant chromatograms.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• The firm has submitted photocopy of Finished Product specification & Test method.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copies of reports of 06 Months Accelerated and 18 Months Real Time Stability Study (30^{o}C$\pm$2 ^{o}C, 65$\pm$5%) Data of 03 Batches of API.</td></tr>
</table>

<table>
<tr><td></td><td></td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API, wherein impurity A has not been tested.</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is similar to innovator's product formulation.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 0.1N, Acetate buffer 4.5, Phosphate Buffer 6.8.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
<tr><td>Brand name</td><td>Forxiga Tab. 5mg</td></tr>
<tr><td>Batch No.</td><td>V832F</td></tr>
<tr><td>Mfg. date</td><td>NIL</td></tr>
</table></td></tr>
<tr><td>57.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for complete stability studies analysis of three batches.</td></tr>
</table>

Remarks of Evaluator:

<table>
<tr><th>Shortcomings communicated</th><th>Response by the firm</th></tr>
<tr><td>The testing/analysis method of API is different from that of manufacturer. Justify.</td><td>90% Tests inclusive of critical tests, i.e ; Assay, Solubility, Related Substance, Clarity, Water content etc. all are comparative / present in Helix's Testing protocols same as supplier. However, test i.e; particle size is for information only & residual solvent (OVI) would be performed in future once the Gas Chromatography is purchased by Quality Control department. However, as per COA, the firm only performed description, identification water content, residue on ignition and assay with in-house claims, and the limits are as per specifications of APi manufacturer.
<table>
<tr><td></td><td>API manufacturer</td><td>FPP manufacturer</td></tr>
<tr><td>Column Condition</td><td>Agilent Zorbax SB-C18 (240mm x 4.6mm x 5 micron or equivalent)</td><td>ODS (150mm x 4.6mm x 5 micron)</td></tr>
</table></td></tr>
<tr><td>The peaks at approx. 1.19, 1.31, 1.50 and 3.73 (RT) are present in the chromatogram of initial assay, but not in that of standard. Justify/clarify.</td><td>The extra small peaks in chromatogram of assay sample is due to presence of excipients which are used in the formulation whereas no extra small peak in chromatogram of standard as the standard contains only pure active ingredient.</td></tr>
<tr><td>The innovator product has time of 15 minutes for dissolution test as per pharmacology and biopharmaceutics review. You have set it 30 minutes. Justify.</td><td>We have formulated our applied product "Aglizon Tablets (Dapagliflozin)" as film coated tablets & as per USP , disintegration time for film coated tablet is NMT 30 minutes for in-vitro test. We have performed In-vitro test not in–vivo.</td></tr>
<tr><td>Tailing factors and theoretical plates are missing in the chromatogram of API and finished product (assay, dissolution and stability data).</td><td>The firm did not submit the same.</td></tr>
</table>

In comparative dissolution profile, justify the use 06 tablets instead of 12 tablets, and the peaks in the chromatograms of samples, which are not present in those of standard.	Please note that the comparative dissolution profile (CDP) of newly applied molecules was carried out in the past by using 06 units. However, we assure you to conduct CDP by using 12 units each of reference and sample product in future & for the same we are in-process to purchase 12 to 14 units dissolution apparatus.
You have not performed drug-excipients compatibility study by submitting that stated composition of developed product is similar to innovator's product formulation. However, you have added talc powder in your formulation, which is not used in the innovator's product. Justify/clarify.	Please note that the Innovator used Talc as excipient in coating process & in our formulation, Talc is used as a Lubricant agent to improve the flow property in granulation stage. This is an inert material which do not have any therapeutic effect & is the part of formulation either used in granulation or coating process. We are enclosing herewith the reference page from Handbook of Pharmaceutical Excipients for Role of Talc for your ready reference in Annex – X.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC: Firm has submitted stability studies of two batches i.e., TF004 & TF 005 for both accelerated and real time conditions at initial and 01 month time points with revised dissolution specifications of "NLT 80% within 15 minutes", along with analytical record i.e., raw data sheets, chromatograms, audit trail reports.

Decision: Registration Board decided to approve registration of "Aglizon 5mg Tablet (Dapagliflozin 5mg) and Aglizon 10mg Tablet (Dapagliflozin 10mg) by M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, SITE Mangho pir Road Karachi-75700. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2251.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 90mg Each film-coated tablet contains: Etoricoxib…90mg (Innovator's specifications)	Form-5 Dy. No: 15706 Dated 07.03.2018 Rs.20,000/- As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were

				advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA			
Drug	Etory Tablet 90mg		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura		
Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
17.	COA of API	Yes
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)

23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:		
Administrative Portion		
39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
40.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information. Batch No.: ACE 01319 Mfg Date: January, 2018 ➢ **Details of ADC attested commercial Invoice** Invoice No. KPLEXP/156/18-19 Quantity imported: 25 Kg Date of import: 22.01.2019 ADC Attestation Date: 30.01.2019 Manufacturer: NOT MENTIONED Batch No.: ACE 01319
41.	Documents for the procurement of reference standard and impurity standards.	No. but CoA of working standard, impurity I and impurity II are attached
42.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.
43.	Mechanism for Vendor pre-qualification	➢ The firm has submitted Vendor evaluation Form. Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.
44.	Certificate of analysis of the API, reference standards and impurity standards	• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.
45.	Documents for the procurement of excipients used in product development?	Yes
46.	List of qualified staff involved in product development with relevant experience.	The firm has submitted list of three qualified staff involved in product development.
Production Data		

<table>
<tr><td>47.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of following documents for development of FPP:
m. Development protocol.
n. Stability Study Protocol.</td></tr>
<tr><td>48.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size/Yield</th></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/790</td></tr>
<tr><td>ETR-PB-010001</td><td>02-2019</td><td>1000/806</td></tr>
<tr><td>ETR-PB-010002</td><td>02-2019</td><td>1000/984</td></tr>
</table></td></tr>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Batch</td><td>Size (tablets)</td><td>Yield (tablets)</td><td>Remaining (tablets)</td></tr>
<tr><td>ETR-PB-010002</td><td>1000</td><td>790</td><td>430</td></tr>
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<tr><td>ETR-PB-010002</td><td>1000</td><td>984</td><td>430</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>The firm has referred to analytical method of the API manufacturer.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Only method for dissolution and HPLC assay.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30ºC±2 ºC, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is qualitatively similar to innovator’s product formulation.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
<tr><td>Brand name</td><td>Etoricoxib Tablet 90mg</td></tr>
<tr><td>Batch No.</td><td>1805005040</td></tr>
<tr><td>Exp. date</td><td>02.2020</td></tr>
</table></td></tr>
<tr><td>57.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Yes</td></tr>
</table>

Remarks of Evaluator:

Shortcomings communicated	Response by the firm
The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.	In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8 As per PAR 85% are results, not limits. Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.
The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.

As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.
You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.
The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2252.	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura	Etory Tablet 120mg Each film-coated tablet contains: Etoricoxib…..120mg (Innovator's specifications)	Form-5 Dy. No 15707 dated 07-03-2019 Rs20,000/- Dated 06-03-2019As per SRO (10's, 20's, 30's)	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg, film-coated tablets. MHRA approved. The firm was inspected on 06.11.2017, **Conclusion:** "Overall the condition

				of the **firm is satisfactory** regarding to building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control they agreed."

STABILITY STUDY DATA			
Drug	Etory Tablet 120mg		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura		
Manufacturer of API	Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India		
API Lot No.	ACE 01319 (MFG DATE: January, 2018)		
Description of Pack (Container closure system)	1x10's, 2x10's, 3x10's in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	ETR-PB-010001	ETR-PB-010002	ETR-PB-010003
Batch Size	1000	1000	1000
Manufacturing Date	02.2019	02.2019	02.2019
Date of Initiation	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)	07.03.2019 (from initial analysis)
No. of Batches	03		
Date of Submission	18.09.2019 (Dy. No. 17862)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
17.	COA of API	Yes
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by DCA, Government of Telangana valid upto 11.05.2019.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

21.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD DRAP Lahore on 30.01.2019, has been submitted.
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes (Stamped only)
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.
40.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has imported Etoricoxib API 25 kg from Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India and the declaration includes the following information. Batch No.: ACE 01319 Mfg Date: January, 2018 ➢ **Details of ADC attested commercial Invoice** Invoice No. KPLEXP/156/18-19 Quantity imported: 25 Kg Date of import: 22.01.2019 ADC Attestation Date: 30.01.2019 Manufacturer: NOT MENTIONED Batch No.: ACE 01319
41.	Documents for the procurement of reference standard and impurity standards.	No. but CoA of working standard, impurity I and impurity II are attached
42.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has provided copy of GMP certificate of M/s Kekule Pharma Limited, MIA, Khazaipally, Jinnaran Mandal, Sangaredddy – 502 319, T. S. India issued by DCA, Government of Telangana valid upto 11.05.2019.
43.	Mechanism for Vendor pre-qualification	➢ The firm has submitted Vendor evaluation Form. Copy of Vendor Certification Questionnaire filled for M/s Kekule Pharma Limited, India.
44.	Certificate of analysis of the API, reference standards and impurity standards	• Copies of COAs of API, working standard and impurity-I and impurity-II have been submitted.

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<tr><td>45.</td><td>Documents for the procurement of excipients used in product development?</td><td>Yes</td></tr>
<tr><td>46.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted list of three qualified staff involved in product development.</td></tr>
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<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Yes</td></tr>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>No, only method for HPLC assay.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Only method for dissolution and HPLC assay.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has also submitted copies of reports of 06 Months Accelerated and 36 Months Real Time Stability Study (30ºC±2 ºC, 75±5%) Data of 03 Batches of API, wherein impurity I and II have not been tested specifically.</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports from manufacturers for all excipients used in product development.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
Firm has stated that composition of developed product is qualitatively similar to innovator’s product formulation.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>pH 1.2 (0.1N HCl), Acetate buffer pH 4.5, Phosphate Buffer pH 6.8 on 06 units. Proof of availability of the product in reference regulatory authorities as defined in 275th meeting of the registration board is required.
<table>
<tr><th>Feature</th><th>Reference product</th></tr>
</table></td></tr>
</table>

			Brand name: Arcoxia tablet 120mg Batch No.: 1805005040 Exp. date: 02.2020
57.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes	

Remarks of Evaluator:

Shortcomings communicated	Response by the firm
The reference product has the criterion for the dissolution test of more than 85% drug release in 15 minutes. You have set it 80% in 30 minutes. Justify.	In Public Assessment Report of Etoricoxib, it is mentioned that release in 0.1N HCl, pH 1.2 is faster i.e more than 85% in 15 minutes and slower in acetate buffer pH 4.5 and phosphate buffer pH 6.8 As per PAR 85% are results, not limits. Conclusion: Etory tablets 90mg and 120mg are released more than 85% in 15 minutes at pH 1.2 and more than 95% in 30 minutes (both sample and reference products) and slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8, f2 values are well above 50% . In case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85% release, not at all points
Specify the exact polymorphic form of API used in the drug product.	Polymorphic Form-1 of API (Etoricoxib) is used. Declaration from manufacturer is attached. (No document specifies that Form-I has been used).
Justify the selection of dissolution parameters for the drug product.	Since innovator brands (Arcoxia 120mg by Frosst Iberica, Spain and Etoricoxib 90mg by Torrent Pharma, UK) and our products Etory Tablets 90mg and Etory Tablets 120mg releases more than 85% in 15 minutes and more than 95% in 30 minutes for both sample and reference products (0.1N HCl, pH 1.2), hence we selected up to 30 minutes for dissolution of our product. Note: Dissolution is slower in acetate buffer pH 4.5 and Phosphate buffer pH 6.8.
The reference product contains Avicel PH 101 and Avicel PH 200 LM; however, you have used Avicel PH 102 in your formulation and have imported Comprecel M 102. Moreover, you have not conducted drug-excipient compatibility studies. Clarify/justify.	We use Arcoxia Tablets (Merck Sharp & Dohme Limited UK) as innovator brand and used excipients same to this brand. - Since we used excipients similar to innovator, hence Drug-Excipient compatibility studies is not required. However, we performed Drug-Excipient compatibility studies by using FTIR and literature survey is also attached.
You have not performed all the tests specified by the CoA of API manufacturer. Justify	Only heavy metals test was missing, now its reagents and apparatus is arranged and test is performed (Report attached)
You have not adjusted the potency of the API (assay = 99.51%) in the drug product.	Potency of API was not adjusted due to pilot batch for R & D, in commercial batches potency will be adjusted.
The batch of API used in the manufacturing of the drug product has not been mentioned in the BMR. Justify.	QC No. is mentioned on BMR, this QC report of API contains all traceable data for API including batch no of API. Now, lot No. of API is mentioned on manufacturing order of BMR.

The humidity graph for accelerated stability chamber, on 08.05.2019 and 09.05.2019 shows out of limit trends. Justification shall be submitted.	Level of water in reservoir was decreased, due to which humidity was decreased from 70% to 60%. Problem was rectified.
As you have performed forced degradation studies of the drug product. Reference shall be provided to the guidelines adopted for the performance of forced degradation studies of the drug product and specificity test in the analytical method validation along with data logger record.	Forced degradation study is performed according to Pharmaceutical manufacturing hand book Pages 566, 571. The firm submitted that in specificity of AMV report, now this is mentioned that there is no effect of degradation products. Although not detected, the two impurities have RT of 1.65 min and 2.68 min, while the drug substance has RT of 3.37.
The values for tailing factor are missing in all the chromatograms of the dossier.	Tailing factor value was not selected in report format, now it is added in report format and few sample graphs are attached.
You have specified impurity I and II for the API. However, these impurities are not specifically tested in CoA provided by the drug substance manufacturer.	These impurities were supplied by manufacturer on our demand for additional test, so they provided. They claimed that these impurities are not present in API, so they are not performing this test.
The reference product is tested in terms of description, identification, colour, average weight, dissolution, uniformity of dosage units by mass variation, related substances, assay, water content, residual solvents and microbial quality. You have not tested the related substances, water content, residual solvents and microbial quality of the drug product. Clarify.	- Related substances test performed and report attached with impurities report of "not detected". - Loss on drying test performed. However, the testing method is not provided. - The firm submitted that the Microbial test performed (analyzed in sister concern company McOlson), report attached. However, the testing method is not provided. - Residual solvent analysis not performed due to non-availability of GC
Provide CDP data for all three physiological buffers, i.e., 0.1N HCl pH 1.2, Acetate buffer pH 4.5, Phosphate Buffer pH 6.8.	The firm submitted CDP data acquired after communication of shortcomings letter. release, not at all points. The firm has performed dissolution on 06 tablet, wherein CV (%) of drug release is ca. 18% and 23% for acetate and phosphate buffers at 15 minutes for the trial batch, i.e., more than 10%. Moreover, in case of drug release less than 85% in 15 minutes, the CDP shall be applied on the drug release data to the extent of one point above the >85%.

Decision of 293rd meeting: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Response by Firm: Firm has submitted stability studies at both accelerated and long term conditions with revised specifications of Dissolution i.e., "NLT 85% within 15 minutes" at initial and one month time point. Details are as follows:

Etory 90 mg tablet:

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	96.26%
			ETR-TB-010002	95.57%	97.96%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-010001	95.75%	99.27%
			ETR-TB-010002	95.57%	98.81%

Etory 120mg tablet

Storage Conditions	Test Performed	Specifications	Batch No.	Initial	01 Month
Accelerated (40±2 ^{0}C, 75±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.82%
			ETR-TB-011002	100.16%	99.43%
Real Time (30±2 ^{0}C, 65±5% RH)	Dissolution Test (at 15 minutes)	NLT 85% of label claim	ETR-TB-011001	100.17%	100.06%
			ETR-TB-011002	100.16%	100.55%

Decision: Registration Board decided to approve registration of "Etory Tablet 90mg (Etoricoxib) and Etory Tablet 120mg (Etoricoxib) by M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26-km Lahore-Sharaqpur Road Sheikhupura. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2253.	M/s. Macter International Limited, F-216, S.I.T.E, Karachi.	Vireof-N 25mg Tablets. Each film coated tablet contains: Tenofovir alafenamide (as fumarate)… 25mg	Duplicate dossier	Approved in US-FDA The firm was granted GMP certificate based on inspection conducted on 14-03-2017.

STABILITY STUDY DATA	
Drug	Vireof-N 25mg Tablets.

Name of Manufacturer	M/s. Macter International Limited, F-216, S.I.T.E, Karachi		
Manufacturer of API	Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai.		
API Lot No.	DBH251-B15A-180802		
Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1, 3,6 (month) Real Time: 0,1, 3,6 (month)		
Batch No.	001P	002P	003P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	Sep- 2018	Sep- 2018	Sep- 2018
No. of Batches	03		
Date of Submission	15-04-19 (Dy. No. 3603)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
17.	COA of API	Applicant has submitted the following: **Copy of COA** **From**:Shengai Desano Chemical Pharmaceuticals**Batch No**: DBH251-B15A-180802
18.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: Copy of GMP Certificate: **Certificate No:** SH2017046 **Issued To**: Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai. **Issued ON**: 04-12-2017 **Valid Till**: 3-12-2022 **Issued By**: China Food & Drug Administration.
19.	Protocols followed for conduction of stability study and details of tests.	Yes
20.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
21.	Documents confirming import of API etc.	Applicant has submitted Coy of Commercial invoice attested by ADC on 27-08-18 having following information on it: **Invoice Number**: DL-Y-2018-0208 **Manufacturer of API**: Desano Limited. No. 1479, Zhangheng Road, Zhangliang Hi- Tech Park, Shanghai 201203, China. Tenofovir Alafenamide Fumarate API: 1kg Tenofovir Alafenamide Fumarate API W/S: 4g

		Impurity 1: 100mg Fumaric acid: 100mg Impurity 2: 100mg
22.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
23.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
24.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Vireof-N Tablet 25mg (TenofovirAlafenamide Fumarate) Tablets by M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 14th Nov, 2019.
Investigation Date and Time: 18th December, 2019.
Investigation Site: M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Macter International Ltd., F-216, S.I.T.E, Karachi for registration of Vireof-N Tablet 25mg (Tenofovir Alafenamide Fumarate) Tablets. PE&R Division considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and also advised to verify:

"Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM".

Composition of Panel:

7. Prof. Dr. Ghulam Sarwar, ex-member Registration Board, Dean faculty of Pharmacy, Jinnah University for Women, Karachi.
8. Dr. Affan Ali Qureshi, Assistant Director (CDL) DRAP, Karachi.
9. Dr. Kirshan Das, Assistant Director DRAP Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

S. No.	Question	Observation
75.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate API including approval from DRAP?	The firm has imported 1Kg Tenofovir Alafenamide Fumarate (API) from Shanghai Desano Chemical Pharmaceutical Co., Ltd.)vide invoice No. DL-Y-2018-0208 dated: 27.08. 2018. There is proper approval from DRAP Karachi Form 6 (2440-17).
76.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer of API is the vendor evaluation process based on audit and other criteria like manufacturer GMP status, DMF source etc.
77.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate reference standard and impurity standards?	The firm has imported Tenofovir Alafenamide Fumarate working standard and two impurities standards from the API manufacturer.
78.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has Certificate of Analysis of API, working standard of API and impurities standards.
79.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificates for API manufacturer issued by China Food & Drugs Administration valid till 03/12/2022.
80.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method of testing.
81.	Do you have stability studies reports on APIs?	The firm has stability studies report on API (Tenofovir Alafenamide Fumarate) conducted by API manufacturer.
82.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of API has performed the stability studies as per SIM method. The process related impurities and degradation product ie. Impurity I have been observed.
83.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying impurities.
84.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API (Tenofovir Alafenamide Fumarate) working standard and impurity standard.
85.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Microcrystalline cellulose, Lactose Monohydrate ,Croscarmellose sodium, Magnesium stearate
86.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
87.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records for the excipients used.
88.	Do you have written and authorized protocols for the development of Tenofovir Alafenamide Fumarate Tablets?	The firm has written and authorized protocol for the development Tenofovir Alafenamide Fumarate Vireof-N tablets 25mg.
89.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug Excipient compatibility studies as composition of their product is similar to that of innovator product (VEMLIDY tablets 25mgfrom GILEAD Ontario Canada.
90.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of their product with VEMLIDY 25mg batch # CBNKMD of GILEAD and found comparable to the innovator product.

<table>
<tr><td>91.</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with requisite manufacturing, storage and analysis facilities.</td></tr>
<tr><td>92.</td><td>Do you have necessary equipments available in product development section for development Tenofovir Alafenamide Fumarate Tablets?</td><td>The firm has all the necessary equipment available in product development section for the development of Tenofovir Alafenamide Fumarate tablets now, however, the product in question was manufactured in routine production area.</td></tr>
<tr><td>93.</td><td>Are the equipment in product development section qualified?</td><td>The equipments in product development section and production area are qualified.</td></tr>
<tr><td>94.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>95.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff in PD section with proper knowledge and training in Product Development including 04 Pharmacists 05 MSc Chemistry and 01 M.Phil.</td></tr>
<tr><td>96.</td><td>Have you manufactured three stability batches for the stability studies of Tenofovir Alafenamide Fumarate Tablets required?</td><td>The firm has manufactured three stability batches as follows;
Tenofovir Alafenamide Fumarate 25mg tablets:
<table><tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr><tr><td>1</td><td>001P</td><td>5000</td></tr><tr><td>2</td><td>002P</td><td>5000</td></tr><tr><td>3</td><td>003P</td><td>5000</td></tr></table>The tablets are packed in Alu Alu blisters with pack size 3 x 10’s.</td></tr>
<tr><td>97.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of tablets required per testing frequency and number of testing frequencies.</td></tr>
<tr><td>98.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete records of production of stability batches. All log books are properly maintained.</td></tr>
<tr><td>99.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for the stability testing of Tenofovir Alafenamide Fumarate tablets.</td></tr>
<tr><td>100.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method for testing of stability batches of finish product i.e. Tenofovir Alafenamide Fumarate tablets based on the API method of testing provided by the API manufacturer.</td></tr>
<tr><td>101.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has developed and validated method based on API manufacturer for testing of finished product, so method transfer studies were required.</td></tr>
<tr><td>102.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir Alafenamide Fumarate and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API (Tenofovir Alafenamide Fumarate) and the finished drug Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg.</td></tr>
<tr><td>103.</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of analysis is stability indicating as evidence by forced degradation studies and spiking studies of the two major impurities.</td></tr>
<tr><td>104.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR compliant as per record available with the firm.</td></tr>
</table>

105.	Can you show Audit trail reports on Tenofovir Alafenamide Fumarate testing?	Audit Trail on the testing reports on Tenofovir Alafenamide Fumarate API and Vireof-N tablets 25mg is available.
106.	Do you have some remaining quantities of degradation products and stability batches?	The firm has only remaining quantities of stability batches kept on real-time stability testing.
107.	Do you have stability batches kept on stability testing?	The firm has three lab scale batches kept on stability studies for real time stability testing. Currently 12 months studies have been completed with satisfactory results.
108.	Do you have valid calibration status for the equipment used in Tenofovir Alafenamide Fumarate Tablets production and analysis?	The firm has valid calibration status for the equipment used in Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg production and analysis.
109.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system for stability chambers.
110.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipments, personnel and utilities are GMP compliant.
111.	Any other query raised by PE&R Division: Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM.	As per firm they have adopted Dissolution method as recommended by US-FDA. The medium is 50 mM Sodium Acetate buffer pH 4.5, Apparatus is USP type II, RPM is 75 which are same as recommended by USFDA. The sampling time is 30 mins which is the maximum time point mentioned on the website of USFDA under dissolution data, however the NDA document of VEMLIDY shows the sampling time to be 15 mins. The firm states that F2 was calculated in CDP at 10 mins because the drug was dissolved more than 90% within 5 mins which shows the formulation complies with innovator as well as US-FDA recommendation. The firm has also performed dissolution testing on an additional time point of 15 month of stability studies and observed the result at 15 minutes and found more than 90% release, which complies with innovator and US-FDA recommendations.

Conclusions:

11. On the basis of risk based approach the genuineness / authenticity of stability data including dissolution method submitted by the firm for registration of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg is verifiable satisfactory level.
12. The related manufacturing area, equipments, personnel and utilities are GMP compliant and well suited for the manufacturing of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg.
13. The case is submitted before Registration Board for decision please.

Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Sr. No.	Deferred for :	Submitted following:
3.	Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15	Applicant has submitted stability studies data for following three batches at following time points: **Batches:** Batch No: P004, P005, P006 **Testing Frequency:**

	minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.	Initial: 1 month: real time plus accelerated. Sampling Time: 15 minutes Drug release at 15 minute sampling interval: Above 90% for all trials at Ist month, as per data submitted by the firm. However data submitted by the firm is in dates before the meeting was carried out & decision of the case was made.

Decision of 295th meeting: Deferred for clarification since the dissolution testing at 15 minutes time point for 2 batches was carried out before the date of conduction of 293rd meeting of Registration Board.

Firm's response: We would like to clarify that the new batches 004P, 005P & 006P were manufactured on 20th December, 2019 immediately after the Product specific Panel inspection held on 17th, December, 2019 on behalf of detailed discussion with panel members. We are also enclosing copy of Form-06 & consumption report of API (for your ready reference). Also it is our usual practice to perform product development activities before launching of the product. We hope that the above justification will be sufficient to clarify the situation.

Decision: Registration Board decided to approve registration of "Vireof-N 25mg Tablets (Tenofovir alafenamide (as fumarate)) by M/s. Macter International Limited, F-216, S.I.T.E, Karachi. Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

i. Verification of stability study data

2254	**Name and address of manufacturer / Applicant**	**"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"**
	Brand Name +Dosage Form + Strength	Boschofen 400mg Infusion
	Composition	"Each 100ml Vial Contains: Ibuprofen……400mg"
	Diary No. Date of R& I & fee	Dy. No 12247 dated 03-04-2018 Rs.20,000/- Dated 28-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Inbufin infusion of M/s Searle IV solutions (Reg.#094023)
	GMP status	GMP inspection dated 03-12-2018 concluding acceptable level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Boschofen 400mg Infusion
Name of Manufacturer	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
Manufacturer of API	Ibuprofen: M/s Pharmagen Ltd., Lahore, Pakistan.
API Lot No.	00510211/001/2018
Description of Pack (Container closure system)	Transparent glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	TR-BFI-02	TR-BFI-03	TR-BFI-04
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		
Date of Submission	06-05-2019 (Dy. No. 5265)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate for M/s Pharmagen Ltd. Lahore, issued on the basis of inspection conducted on 08-01-2019
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	--
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Boschofen 400mg/100ml (Ibuprofen) Infusion by M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 26th, December, 2019.
Investigation Date and Time: 8th July, 2020 (Afternoon).
Investigation Site: Factory premises of M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

Background:
Chairman Registration Board considered the applications of M/s Bosch Pharmaceutical, Bosch House 221, Sector 23, Korangi Industrial Area, Karachi for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

13. Dr. Rafeeq Alam Khan, Meritorious Professor, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
14. Dr. Sanam Kausar Jahan, Assistant Director, CDL, DRAP, Karachi.
15. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

S. No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Firm has procured 0.4kg Ibuprofen from M/S Pharmagen ,Lahore
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which includes GMP Status, provision of DMF, reference standard, impurity standards etc.
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	The firm has obtained API reference standard from API manufacturer.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs and working standards
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided GMP certificate issued by Drug Regulatory Authority of Pakistan.
Q.No.6	Do you use API manufacturer method of testing for testing API?	The firm has used the manufacturer method of testing of API to carryout analysis.
Q.No.7	Do you have stability studies reports on API?	The firm has stability studies reports from API manufacturer conducted on 03 batches for accelerated and real time condition.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability data of API provided by manufacturer is stability indicating and degradation products has been quantified.
Q.No.9	Do you have method for quantifying the impurities in the API?	The firm has used the analysis method provided by the manufacturer of API for quantification of impurities in API.
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had arranged 0.4kg of Ibuprofen API out of which 0.07 kg was still available in firm .Remaining quantities of working standard and impurity standards were also available.
Q.No.11	Have you used pharmaceutical grade excipients?	The firm used pharmaceutical grade excipients.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm has proper documents for import of the used excipients.
Q.No.13	Do you have test reports and other records on the excipients used?	The firm has Analytical reports for all excipients used in product development of Boschofen infusion.
Q.No.14	Do you have written and authorized protocols for the development of applied product?	The firm had written and authorized protocol for development of Boschofen infusion .
Q.No.15	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator's product and also stability studies have not shown any incompatibility or significant degradation.

Q.No.16	Have you performed comparative dissolution studies?	Not Applicable.
Q.No.17	Do you have product development (R&D) section	The firm has dedicated area for product development.
Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	The firm has necessary equipment for manufacturing of stability batches.
Q.No.19	Are the equipments in product development section qualified?	All equipment in product development section is qualified.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance /calibration plan for equipment in product development section and maintenance /calibration are carried out accordingly.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff in product development section with relevant work experience.
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	Firm has manufactured three stability batches for the stability studies of Boschofen infusion. Batch No : TR-BFI-02 Batch No : TR-BFI-03 Batch No : TR-BFI-04
Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of vials per testing and the number of vials required for whole stability testing.
Q.No.24	Do you have complete record of production of stability batches?	The firm has complete record for manufacturing of three batches of Boschofen Infusion.
Q.No.25	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of stability batches.
Q.No.26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated the method for the testing of Boschofen infusion.
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has complete record of qualification of equipment's /instruments used for test and analysis of API and Boschofen infusion .
Q.No.29	Is your method of analysis stability indicating?	The method of analysis for finished product is stability indicating .
Q.No.30	Is your HPLC software is 21CFR compliant? (Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.))	The HPLC used for analysis of stability batches is Water e2650 with auto sampler and gradient system and it was 21CFR compliant as per record available with firm.

Q.No.31	Can you show Audit Trail reports on stability studies testing?	The firm has demonstrated the audit trail reports for the data submitted for Boschofen infusion.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	The firm had some remaining quantities of stability batches.
Q.No.33	Do you have stability batches kept on stability testing?	The firm has completed accelerated studies whereas, samples are kept for real time stability studies.
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	The firm has valid calibration status for all the equipment /instruments used in production and analysis of the Boschofen infusion .
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	The firm has two separate Stability chambers for Real time and accelerated studies which are equipped with data loggers.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area ,Equipment ,personnel and utilities can be rated as cGMP compliant

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Boshofen 400mg/100ml (Ibuprofen) Infusion is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Boshofen 400mg/100ml Infusion.

Decision: Registration Board decided to approve registration of "Boschofen 400mg Infusion (Ibuprofen) by M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

2255.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5738: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/850 Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's,14's, 20's, 28's, & 30's
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/850mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/850mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted comparative dissolution profile of applied product against the reference product, instead firm has submitted CDP data for the higher strength i.e., Xiga-met 5/1000 against the reference product Xigduo.

STABILITY STUDY DATA	
Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	XMA-T5-19	XMA-T6-19	XMA-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

2256.	**Name, address of Applicant / Marketing Authorization Holder**	**Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.**
	Name, address of Manufacturing site.	Name: M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5739: 09-05-2019
	Details of fee submitted	PKR 50,000/-: 09-05-2019
	The proposed proprietary name / brand name	**Xiga-Met 5/1000 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin as propanediol monohydrate …… 5mg Metformin HCl ….. 850mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Drugs Used in diabetes, combinatiom of oral blood glucose –lowering drugs
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's,14's, 20's, 28's, & 30's
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Xigduo 5/1000mg of EMA approved
	For generic drugs (me-too status)	Dapa-Met Tablet 5mg/1000mg of M/s Hilton Pharma
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Remarks: The Finished product analytical method validation report has been prepared and approved in 08-2019, while as per relevant guidelines the method validation has to be performed before commencing stability studies. Firm has committed to perform test method validation before commencing of stability studies for future developed products.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution profile of applied product against the reference product, Xigduo (batch# X1888A) in three buffers i.e., pH 1.2, pH 4.5 & pH 6.8 with acceptable value of f2 factor.
STABILITY STUDY DATA		

Manufacturer of API	**Dapagliflozin propanediol monohydrate:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province, China **Metformin HCl**: M/s Wanbury Limited, Andhra Pradesh, India		
API Lot No.	**Dapagliflozin propanediol monohydrate:** 180903 **Metformin HCl**: MT13881218		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	XMB-T5-19	XMB-T6-19	XMB-T7-19
Batch Size	2000 tabs.	2000 tabs.	2000 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	04-2019	04-2019	04-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of invoice (invoice# HN190124-C) cleared by DRAP Lahore office dated 01-02-2019 specifying import 5Kg Dapagliflozin (batch#180903). **Metformin HCl:** Firm has submitted copy of invoice (invoice# 92002215) cleared by DRAP Lahore office dated 19-12-2018 specifying import 1.3Kg Metformin HCl (batch# MT13881218).
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The stability studies upto 3rd month have been performed with limits of Q = 70%, while at 6th month firm has rectified the specifications as Q = 80%.
- Firm has applied have applied Paddle speed = 100 RPM in dissolution parameters for zero & 3rd month stability study but has revised our Product test method (PTM) with agitation speed of 75 rpm and 6th month stability study was performed as per revised PTM.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Xiga-Met 5/1000 Tablet & Xiga-Met 5/850 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.

Date of Inspection	2nd – 3rd July, 2020
Purpose of Inspection	Verification of authenticity of stability data for purpose of registration of drugs with reference DRAP's letter no. F.1-2/2020-PEC dated 22-04-2020.
Name of Inspector	01. Dr. Muzammal Waheed Director, DTL, Faisalabad. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Hafiz Ahsan Assistant Director, DRAP, Islamabad.

Q. No.	Contents	Remarks
73	Do you have documents confirming the import of Dapagliflozin Propanediol Monohydrate and Metformin HCl including approval from DRAP?	**Dapagliflozin Propanediol Monohydrate:** The firm has imported Dapagliflozin Propanediol Monohydrate raw material vide invoice no. HN190124-C dated 24-01-2019 from M/s. Fuxin Long Rui Pharmaceutical Co., Ltd., China and got DRAP approval vide no. 1757/2019/DRAP dated 01-02-2019. **Metformin Hydrochloride:** The firm has imported Metformin HCl raw material vide invoice no. 92002215 dated 10-12-2018 from M/s. Wanbury Ltd., India and got DRAP approval vide no. 16536/2018/DRAP dated 19-12-2018.
74	What was the rationale behind selecting the particular manufacturer of API?	The firm selected API manufacturers based on their vendor evaluation mechanism.
75	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Dapagliflozin Propanediol Monohydrate working standard from API supplier dated 27-06-2019. The firm imported Metformin HCl working standard and impurity standard (Metformin HCl Compound A) from API supplier dated 28-05-2019.
76	Do you have certificate of Analysis of the API, reference standards and impurity standards?	**Dapagliflozin Propanediol Monohydrate:** The firm has certificates of analysis for API and working standard. **Metformin HCl:** The firm has certificates of analysis for API, working standard and impurity standard.
77	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	**Dapagliflozin Propanediol Monohydrate**: The firm has valid GMP Certificate of M/s. Fuxin Long Rui, China issued by Fuxin Food & Drugs Administration, China valid till 27-09-2020.

		Metformin HCl: The firm has valid GMP Certificate of M/s. Wanbury Ltd., India issued by Directorate of Drugs Control Administration, Andhra Pradesh valid till 06-02-2022.
78	Do you use API manufacturer method of testing for testing APIs?	The firm has used API manufacturer's method of testing. *Moreover, the firm was advised to develop method transfer protocol for testing APIs.*
79	Do you have stability studies reports on APIs?	The firm had stability studies reports of APIs from API manufacturer: **Dapagliflozin Propanediol Monohydrate**: Accelerated (40ºC±2ºC/RH75%±5%) –6 months Real time (30ºC±2ºC/RH65%±5%) – 24 months **Metformin HCl:** Accelerated (40ºC±2ºC/RH75%±5%)– 6 months Real time (30ºC±2ºC/RH75%±5%) – 60 months
80	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer had performed stability as per SIM method and Metformin HCl Compound A impurity had been quantified.
81	Do you have method for quantifying the impurities in the API?	The firm had testing method to quantify Metformin HCl Compound A impurity as provided by API manufacturer.
82	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Nil.
83	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Avicel pH 102, Klucel EXF, Polyvinylpyrolidone, Aerosil 200, Magnesium stearate, Opadry AMB purple (88A200006) and Opadry white (85G28725).
84	Do you have documents confirming the import of the used excipients?	The firm had necessary documents confirming the import of the used excipients.
85	Do you have test reports and other records on the excipients used?	The firm had certificates of analysis of the excipients used.
86	Do you have written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?	The firm had written and authorized protocols for the development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.
87	Have you performed Drug-excipient compatibility studies?	The firm had performed drug-excipient compatibility studies under stress conditions of 60ºC ± 2ºC / RH 75% ± 5%.
88	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Xiga-Met 5/1000 Tablet with Xigduo 5/1000 Tablet, manufactured by M/s. AstraZeneca, USA using paddle apparatus at 100rpm in 900ml of the following dissolution mediums: 7. HCl buffer 8. Acetate buffer 9. Phosphate buffer

<table>
<tr><td>89</td><td>Do you have product development (R&D) section</td><td>The firm had product development (R&D) section.</td></tr>
<tr><td>90</td><td>Do you have necessary equipment available in product development section for development of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet?</td><td>Product development section has necessary equipment to develop Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet.</td></tr>
<tr><td>91</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section were qualified however, the firm was advised to perform qualifications of equipment from authorized bodies.</td></tr>
<tr><td>92</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.</td></tr>
<tr><td>93</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Yes.</td></tr>
<tr><td>94</td><td>Have you manufactured three stability batches for the stability studies of Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablet as required?</td><td>The firm has manufactured three initial stability batches for the stability studies of Xiga-Met 5/850 Tablet with batch numbers i.e. XMA-T5-19, XMA-T6-19 and XMA-T7-19 and of Xiga-Met 5/1000 Tablet with batch numbers i.e. XMB-T5-19, XMB-T6-19 and XMB-T7-19. The accelerated studies were done in Climatic test chamber (Model: HPP-749; Making Memmert, Germany) and long-term studies were done in Climatic test chamber (Model: HPP-750, Making Memmert, Germany).</td></tr>
<tr><td>95</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm had followed in-house SOP for fixing the batch size of stability batches.</td></tr>
<tr><td>96</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td colspan="3">Xiga-Met 5/850 Tablets</td></tr>
<tr><td>XMA-T5-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMA-T6-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMA-T7-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td colspan="3">Xiga-Met 5/1000 Tablets</td></tr>
<tr><td>XMB-T5-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMB-T6-19</td><td>2,000</td><td>03-2019</td></tr>
<tr><td>XMB-T7-19</td><td>2,000</td><td>03-2019</td></tr>
</table></td></tr>
<tr><td>97</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm had protocols for testing of stability batches.</td></tr>
<tr><td>98</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had developed method of Xiga-Met 5/850 Tablet (RD-PTM-16 C) and Xiga-Met 5/1000 Tablet (RD-PTM-17 C) and validated the test method (CCL-AMVR-220) for testing of stability batches.</td></tr>
</table>

<table>
<tr><td>99</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable.</td></tr>
<tr><td>10</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Dapagliflozin Propanediol Monohydrate and Metformin HCl API and the finished drug?</td><td>The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished product. However, the firm was advised to qualify the equipments / instruments from authorized bodies.</td></tr>
<tr><td>10</td><td>Do your method of analysis stability indicating?</td><td>The firm had conducted stress testing of finished product.</td></tr>
<tr><td>10</td><td>Do your HPLC software 21CFR Compliant?</td><td>API testing, FPP testing and compatibility testing had been conducted on HPLCs which were not 21 CFR compliant.
However, the firm has procured 21 CFR part 11 compliant HPLC.</td></tr>
<tr><td>10</td><td>Can you show Audit trail reports on Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 testing?</td><td>Initially, audit trail was not enabled. However, log of data was available on the HPLCs. The data was also checked through hard copies of chromatograms.
However, 6 months onwards stability studies were performed on audit trail active software.</td></tr>
<tr><td>10</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches kept on stability testing:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Tablets used for stability studies</th><th>Remaining Quantities of Stability Btaches</th></tr>
<tr><td colspan="4">Xiga-Met 5/850 Tablets</td></tr>
<tr><td>XMA-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMA-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMA-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td colspan="4">Xiga-Met 5/1000 Tablets</td></tr>
<tr><td>XMB-T5-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMB-T6-19</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>XMB-T7-19</td><td>2,000</td><td>324</td><td>72</td></tr>
</table></td></tr>
<tr><td>10</td><td>Do you have stability batches kept on stability testing?</td><td>The firm had stability batches kept on stability testing.</td></tr>
<tr><td>10</td><td>Do you have valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 Tablets production and analysis?</td><td>The firm had valid calibration status for the equipment used in Xiga-Met 5/850 Tablet and Xiga-Met 5/1000 production and analysis.</td></tr>
<tr><td>10</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Adequate monitoring and control was available for stability chamber. The firm was advised to improve alarm system.</td></tr>
<tr><td>10</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>Requisite facilities are satisfactory and GMP compliant (DRAP ref. no. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 valid for 3 years).</td></tr>
</table>

VERIFICATION:

(iii) The firm selected M/s. Fuxin Long Rui Pharmaceutical Co. Ltd., China for Dapagliflozin Propanediol Monohydrate based on their vendor evaluation mechanism. Panel verified following documents regarding source:

- ADC attested invoice
- Trial cards

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. CCL Pharmaceuticals (Pvt.) Ltd., at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan have conducted stability studies of the following products. However few points are being recorded for the kind perusal of the Drug Registration Board, against questions 6, 19, 28, 30, 31 and 35 of the check list.

Decision: Registration Board decided to approve registration of "Xiga-Met 5/850 Tablet & Xiga-Met 5/1000 Tablet by M/s CCL Pharmaceuticals (Pvt.) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

d. Exemption from onsite verification of stability data

2257.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.**
	Brand Name +Dosage Form + Strength	**Lina 5mg tablets**
	Composition	Each film coated tablet contains: Linagliptin ……5mg
	Diary No. Date of R& I & fee	Dy. No 1271 dated 28-11-2016, Rs.50,000/- 24-11-2016
	Pharmacological Group	Anti-diabetes
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Lina 5mg tablets
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura.
Manufacturer of API	M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China
API Lot No.	161031
Description of Pack (Container closure system)	Alu/Alu blister in unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH
Time Period	Accelerated: 6 months

	Real Time: 6 months		
Frequency	Accelerated: 0,1,2,3,4,5,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	LNA-PB-005002	LNA-PB-005003	LNA-PB-005004
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	December 2017	December 2017	December 2017
Date of Initiation	December 2017	December 2017	December 2017
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	• Copy of COA for Linagliptin (Batch# 161031) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
161031	HK1701121-B	80gm	20-03-2017

All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Lina tablets 5mg and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 09-05-2019 (R&I no. 5661)

Administrative Portion

39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Lansodex capsule 30mg and 60mg, Sofos Tablet 400/90mg and 400mg", which was conducted on 10.02.2018, and was presented in 287th meeting of Registration Board. Following observations were reported in the report: vii. The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA

<table>
<tr><td></td><td></td><td>viii. The firm has audit trail Reports on testing.
ix. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software.</td></tr>
<tr><td>40.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Commercial invoice for import of Linagliptin approved by DRAP office, Lahore has been submitted as per following details
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th><th>Date of approval by DRAP</th></tr>
<tr><td>161031</td><td>HK1701121-B</td><td>80gm</td><td>20-03-2017</td></tr>
</table></td></tr>
<tr><td>41.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>No document has been submitted to establish the procurement of reference standard and impurity standards.</td></tr>
<tr><td>42.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted copy of DML (Liao20150233) for the M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China, issued by Liaoning province Food & Drug Administration valid upto 20-12-2022.</td></tr>
<tr><td>43.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted document of “Rationale for Selection of manufacturer of API ‘Linagliptin’”</td></tr>
<tr><td>44.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>The firm has submitted certificate of analysis for API, working standard & impurity standards.</td></tr>
<tr><td>45.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>46.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in Research & product development & scientific Development and Analytical services comprising of 19 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>47.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted authorized photocopy of Product Development Protocol & Stability protocols for applied product.</td></tr>
<tr><td>48.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Lina 5mg tablet such as.
<table>
<tr><th colspan="3">Lina 5 mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>LNA-PB-005002</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005003</td><td>12-2017</td><td>2000 Tablets</td></tr>
<tr><td>LNA-PB-005004</td><td>12-2017</td><td>2000 Tablets</td></tr>
</table></td></tr>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning details of the remaining quantities of tablets kept at accelerated and real time stability studies.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical charts for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
</table>

<table>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Linagliptin.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Specification/Testing Method of Finished Product for Lina 5mg tablets along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc. for applied formulation.</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Linagliptin</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Lina 5mg tablet.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has stated that they have similar qualitative formulation as that of the innovator product.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted results for comparative dissolution results in 0.1N HCl buffer against the reference product “Tradjenta tablets 5mg”.
<table><tr><th>Feature</th><th>Reference product</th><th>Product of M/s Jenner</th></tr><tr><td>Brand name</td><td>Tradjenta tablets 5mg</td><td>Lina 5mg tablet</td></tr><tr><td>Batch No.</td><td>655575</td><td>LNA-PB-005002</td></tr></table>• Firm has submitted f2 factor value for each time point.</td></tr>
<tr><td>57.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted method audit trail reports of stability studies of applied formulations.</td></tr>
</table>

Remarks of Evaluator:

Sr. #	Observations	Response of Firm
1	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) as written in finished product specifications	The analysis is performed for sample solutions and standard solutions in dissolution is 0.005mg/ml as already mentioned in whole stability studies testing records. In finished product specifications, by typing mistake, 2ml is written instead of 1 ml which lead to read as 0.01mg/ml instead of 0.005mg/ml. (It is just typing mistake and is rectified)
2	Retention time of 1st Month stability studies is about 5 mints whereas on all other time points is about 3 mints	Retention time at whole stability studies is about 3 mints instead of 1st Month time point analysis, which is about 5 minutes. **Remarks:** The pressure of HPLC column was increased at 1st Month analysis time point due to which retention time for both sample and standard solution was increased to about 5 minutes from 3 minutes. After that we rectified it and separate column is specified for whole stability studies of said product. Further, more analytical method validation is performed and retention time during AMV was also about 3 minutes.
3	Concentration of sample solution (0.005mg/ml) is different from standard solution (0.01mg/ml) in dissolution at 1st month time point analysis	As earlier discussed in point 3, In finished product specifications, by typing mistake, 2ml is written instead of 1 ml.

		The problem was rectified and analysis at all time points were performed at 0.005mg/ml concentration after this time point.

Decision of 296th meeting: Registration Board decided to approve registration of "Lina 5mg tablets (Linagliptin)" by M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore-Sharaqpur Road, District Sheikhupura. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration letters shall be issued after decision on comments of IPO regarding patent matter for the applied formulation.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2258	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43103 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA			
Drug	Jarzin-Met 5/850mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/19030439		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	May 2019	May 2019	May 2019
Date of Initiation	May 2019	May 2019	May 2019
Batch Nos.	**19PD-109**	**19PD-119**	**19PD-120**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd.

	(Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2259	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/500mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43106 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA

STABILITY STUDY DATA

Drug	Jarzin-Met 12.5/500mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.
API Lot No.	**Empagliflozin**: 20181001002 **Metformin**: MEF/18102071
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton

Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH			
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months			
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)			
Manufacturing date	Feb 2019		Mar 2019	Mar 2019
Date of Initiation	Mar 2019		Mar 2019	Mar 2019
Batch Nos.	**19PD-039**		**19PD-065**	**19PD-067**
Batch Size	1,500 Tablets		1,500 Tablets	1,500 Tablets
No. of Batches	03			
DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)				
DOCUMENTS TO BE PROVIDED			**STATUS**	
COA of API			Yes	
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.			**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.	
Protocols followed for conduction of stability study and details of tests.			Yes	
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.			Yes	
Documents confirming import of API etc.			**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg	
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.			Yes	
Commitment to continue real time stability study till assigned shelf life of the product.			Yes	
Commitment to follow Drug Specification Rules, 1978.			Yes	
Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2260	M/s The Searle Company Limited	Jarzin-Met 12.5/1000mg Tablets	Form-5D Dy. No: 43104 Dated. 18-Dec-2018	SYNJARDY TABLETS Approved by USFDA

	F-319 S.I.T.E. Karachi, Pakistan.	Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl ……. 1000mg Anti-Diabetes Mfg. Specs.	Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	

STABILITY STUDY DATA			
Drug	Jarzin-Met 12.5/1000mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.	**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19010053		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	03 2019	04 2019	04 2019
Date of Initiation	04 2019	05 2019	05 2019
Batch Nos.	**19PD-087**	**19PD-100**	**19PD-102**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg

			Empagliflozin: Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg	
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.			Yes	
Commitment to continue real time stability study till assigned shelf life of the product.			Yes	
Commitment to follow Drug Specification Rules, 1978.			Yes	
Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**
2261	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 12.5/850mg Tablets Each film-coated tablet contains: Empagliflozin …. 12.5mg Metformin HCl……. 850mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43105 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS Approved by EMA
STABILITY STUDY DATA				
Drug		Jarzin-Met 12.5/850mg Tablets		
Name of Manufacturer		M/s The Searle Company Limited.		
Manufacturer of API		**Empagliflozin**: M/s Anhui Youcare Kayue Pharmaceutical Co., Ltd., China **Metformin**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.		
API Lot No.		**Empagliflozin**: 20181001002 **Metformin HCl**: MEF/19030439		
Description of Pack (Container closure system)		Alu-Alu Blister in unit carton		
Stability Storage Condition		**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency		**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date		04 2019	04 2019	May 2019
Date of Initiation		May 2019	May 2019	May 2019
Batch Nos.		**19PD-105**	**19PD-106**	**19PD-108**
Batch Size		2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT (M/s The Searle Company Limited.)				
DOCUMENTS TO BE PROVIDED			**STATUS**	
COA of API			Yes	
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.			**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023.	

	Empagliflozin: Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.

29.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
30.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
31.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
32.	Stability study data of API from API manufacturer	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.
33.	Approval of API/ DML/GMP certificate of API manufacturer issued	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of

	by concerned regulatory authority of country of origin.	M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (certificate# AH20150172) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 03-01-2020 has been submitted. Copy of DML (20160049) issued by Anhui Drug administration, China for the M/s Anhui Youcare Kaiyue Pharmaceuticals Co., Ltd. China valid upto 13-12-2020 has also been submitted.
34.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 29-03-2019 Invoice# EXP/2657/18-19 Qty. 3000Kg **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 01-01-2019 Invoice# TM20181225L Batch# 2018001002 Qty. 1Kg
35.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
36.	Method used for analysis of FPP	Submitted
37.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
38.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
39.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
40.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 12.5/850mg Tablets, Jarzin-Met, 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets, Jarzin-Met 5/850mg Tablets.
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator^{II}:		

Sr. No.	**Name and Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification**	**Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size**	**International Availability / Local Availability**	**Evaluated by**

2262	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/500mg Tablets Each film-coated tablet contains: Empagliflozin …… 5mg Metformin HCl …… 500mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43095 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS	AD PEC-II

STABILITY STUDY DATA			
Drug	Jarzin-Met 5/500mg Tablets		
Name of Manufacturer	M/s The Searle Company Limited.		
Manufacturer of API	**Empagliflozin**: M/s Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl:** M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India		
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin HCl**: MEF/17091410		
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton		
Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Apr 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-086**	**18PD-099**	**18PD-090**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
DOCUMENTS TO BE PROVIDED	**STATUS**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg)

	Empagliflozin: Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Previous Remarks of Evaluator:

- Salt from of Metformin is not mentioned in Form 5-D.
- Firm has submitted that "the material Empagliflozin" having batch no. D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.
- Content uniformity test has not been performed for Empagliflozin to determine uniformity of dosage unit.
- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Sr. No.	Name and Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength Composition) Pharmacological Group Finished Product Specification	Type of Form Initial Date Diary Fee including differential fee Demanded Price/ Pack size	International Availability / Local Availability
2263	M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan.	Jarzin-Met 5/1000mg Tablets Each film-coated tablet contains: Empagliflozin…….5mg Metformin HCl …….1000mg Anti-Diabetes Mfg. Specs.	Form-5D Dy. No: 43102 Dated. 18-Dec-2018 Rs. 50,000/- dated 10-12-2018 As per DPC 2×7's	SYNJARDY TABLETS BOEHRINGER INGELHEIM PHARMACEUTICALS

STABILITY STUDY DATA

Drug	Jarzin-Met 5/1000mg Tablets
Name of Manufacturer	M/s The Searle Company Limited.
Manufacturer of API	**Empagliflozin**: Zhejiang Huahai Pharmaceutical Co., Ltd **Metformin HCl**: M/s Aarti Drugs Limited, plot no. 211 & 213, Road no. 2, GIDC, Sarigam, Gujarat, India.
API Lot No.	**Empagliflozin**: D5284-15-001 **Metformin**: MEF/17091410
Description of Pack (Container closure system)	Alu-Alu Blister in unit carton

Stability Storage Condition	**Real Time:** 30˚C ± 2˚C / 75% ± 5%RH **Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:** 0, 3, 6 (Months) **Accelerated:** 0, 3, 6 (Months)		
Manufacturing date	Mar 2018	Apr 2018	Apr 2018
Date of Initiation	May 2018	May 2018	May 2018
Batch Nos.	**18PD-084**	**18PD-087**	**18PD-098**
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT
(M/s The Searle Company Limited.)

DOCUMENTS TO BE PROVIDED	STATUS
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator:

- Salt form of Metformin is not mentioned in Form 5-D.
- The acceptance criteria of dissolution test submitted by firm for applied formulation is NLT 75% (Q) after 30 minutes for both Metformin HCl & Empagliflozin. While the dissolution specification of the innovator product i.e., "Synjardy", revealed in Clinical Pharmacology & Biophartmaceutics review by USFDA (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206111Orig1s000ClinPharmR.pdf) declares the dissolution specification for 20 minutes for all strengths of both drug substances i.e., Metformin HCl & Empagliflozin.
- Firm has submitted that "the material Empagliflozin" having batch no D5284-15-001 from "Zhejiang Huahuai Pharmaceutical Co., Ltd. had a retest date of May-2017. As per our SOP QAD/III/0020, we have retested the above mentioned material on date 29-04-2017. The results complies with specification, on the basis of the satisfactory result we have extended its retest date upto 28-04-2018." Scientific rationale/justification shall be submitted for extending retest date to one year on the basis of analysis performed by the firm.

- Upon communication of above observation the firm has referred to following definition of "re-test period", from Annex 2 (Stability testing of active pharmaceutical ingredients and finished pharmaceutical products) of WHO Technical Report Series, No. 953, 2009:

re-test period
"The period of time during which the API is expected to remain within its specification and, therefore, can be used in the manufacture of a given FPP, provided that the API has been stored under the defined conditions. After this period a batch of API destined for use in the manufacture of an FPP should be re-tested for compliance with the specification and then used immediately. **A batch of API can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification.** For most substances known to be labile, it is more appropriate to establish a shelf-life than a re-test period. The same may be true for certain antibiotics."

- Moreover, firm has submitted that they have not performed "Residual solvents testing" & "Chiral impurity testing" at the time of re-test since both these are process related impurities and if they are within specification than there is no need to further analyze at stability & at re-test.

- It is pertinent to mention that as per applicable guidelines, the API could be used immediately (within one month) after the retest, but one time retest analysis could not be used to extend the shelf life of the API in term of retest date.

- Submitted GMP certificates of API manufacturers, does not mention the names of API being imported.

Decision of 293rd meeting: Registration Board deferred the cases for following reasons:

- Clarification/Justification shall be submitted by the firm for extending shelf life of the API for 1 year on the basis of one-time retest.
- Stability studies of Empagliflozin API from the API manufacturer.
- Submission of revised Form 5 with correct composition, declaring the salt form of Metformin.

Firm's response:

- Firm has referred to their SOP of "Retesting of Raw materials".
- For Empagliflozin firm has submitted both accelerated stability studies (6 months) & long-term stability studies report (36 months) of three batches from the API manufacturer.
- Revised Form 5 D with correct composition, declaring the salt form of Metformin as "Metformin HCl" has been submitted.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION		
Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet and provided the following documents in conjunction with the checklist approved by the Registration Board.		
29.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Tapendol tablets (Tapentadol)", which was presented in 289th meeting of Registration Board held on 14-16 May, 2019 **Observations:** Panel has observed that firm has improved as follows: • The HPLC software is 21CFR compliant as per record available with the firm. • Audit trail on the testing reports is available. • Firm has software for monitoring of stability chambers. **Decision:** Registration Board decided to approve registration of "Tapendol tablets 50mg, 75mg & 100mg by M/s The Searle Company Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
30.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
31.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.

32.	Stability study data of API from API manufacturer	**Metformin HCl:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches. **Empagliflozin:** Firm has submitted both stability studies & long term stability studies reports of three batches
33.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate issued by Food & Drug Control Administration, Gujarat state, India, in the name of M/s AARTI Drugs Ltd. (Unit-II), Gujarat State, India valid upto 19-03-2023. **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180073) issued by China Food & Drug Administration, in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd valid upto 25-06-2023.
34.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 09-10-2017. Batch# MEF/17091410 (Qty. 2000 Kg) **Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC Karachi, dated 07-03-2017 Batch# D5284-15-001 (Qty. 300gm)
35.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols for the development of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
36.	Method used for analysis of FPP	Submitted
37.	Drug-excipients compatibility studies (where applicable)	Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.
38.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
39.	Record of comparative dissolution data (where applicable)	• Firm has performed comparative dissolution studies for 5/1000mg tablet in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Synjardy tablet for all the concluding f2 value within acceptable limit.
40.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted for Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches of Jarzin-Met 5/1000mg Tablets, Jarzin-Met, 5/500mg Tablet
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator^{II}:		
Decision: Registration Board decided to approve registration of "Jarzin-Met 5/1000mg Tablets, Jarzin-Met 5/500mg Tablets, Jarzin-Met 12.5/850mg Tablets, Jarzin-Met 12.5/1000mg Tablets, Jarzin-Met 12.5/500mg Tablets and Jarzin-Met 5/850mg Tablets by M/s The Searle Company Limited F-319 S.I.T.E. Karachi, Pakistan. Manufacturer will place first three commercial batches of all 6 products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

2264.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 800mg Tablets

	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..800mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	
2265.	**Name and address of manufacturer / Applicant**	**"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."**
	Brand Name +Dosage Form + Strength	Esli 200mg Tablets
	Composition	"Each Tablet contains: Eslicarbazepine Acetate……..200mg "
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013 Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 10-7-2019 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Esli Tablet	
Name of Manufacturer	"M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi."	
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India	
API Lot No.	Eslicarbazepine acetate: 17EA00012	
Description of Pack (Container closure system)	Alu-Alu blister	
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Esli 200mg tablet	Esli 800mg tablet
Batch#	ESL-289310-3, ESL-289210-2, ESL-289010-1	ESL-290311-7, ESL-290211-6, ESL-290111-5
Batch Size	1554 Tablets	421 Tablets

Manufacturing Date	Oct-2018	Nov-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Provided
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate # 19061470) issued to M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

Batch No.	Invoice No.	Quantity Imported.
17EA00012	EL/2021700092	2Kg

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Esli 200mg & 800mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

39.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: vii. The HPLC software is 21 CFR compliant. viii. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. ix. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.

<table>
<tr><td>40.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 08-06-2017 for the import of Eslicarbazepine acetate from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India, has been submitted.

<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th></tr><tr><td>17EA00012</td><td>EL/2021700092</td><td>2Kg</td></tr></table></td></tr>
<tr><td>41.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted a non-commercial invoice from M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India for the import of 1000mg of working standard</td></tr>
<tr><td>42.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• The firm has provided copy of GMP ceretificate (Certificate # 19061470) issued to M/s M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India by Hubeii Food & Drug Control Administration Gujarat, valid Up to 01-07-2022.</td></tr>
<tr><td>43.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure”,
SOP No: PDV-FM-068 with effective date 02-03-2018.
Version no: 01
• Copy of “Vendor’s Audit form” filled for M/s CTX Lifesciences Pvt. Ltd., Surat, Gujarat, India</td></tr>
<tr><td>44.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• The firm has submitted certificate of analysis for API (Batch# 17EA00012), working standard (Batch#WS/EA/03) for Eslicarbazepine acetate.</td></tr>
<tr><td>45.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>46.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 17 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>47.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted photocopy of Development Protocol `for Lab scale batch manufacturing of Esli 200mg & 800mg Film coated tablets.<br>• Project code # HPL/10/18/ESL<br>• Issued on Oct, 2018<br>• The SOP mentions` the details of master formulation & manufacturing method for both products. Copies of stability protocols have also been submitted for both products.</td></tr>
<tr><td>48.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Vonopran tablets, such as.

<table><tr><th colspan="3">Esli 200mg Tablet</th></tr><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>ESL-289010-1</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><td>ESL-289210-2</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><td>ESL-289310-3</td><td>Oct-2018</td><td>1554 Tablets</td></tr><tr><th colspan="3">Esli 800mg Tablet</th></tr><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>ESL-290111-5</td><td>Nov-2018</td><td>421 Tablets</td></tr><tr><td>ESL-290211-6</td><td>Nov-2018</td><td>421 Tablets</td></tr><tr><td>ESL-290311-7</td><td>Nov-2018</td><td>421 Tablets</td></tr></table></td></tr>
</table>

<table>
<tr><td>49.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet for all trial batches of both Esli 200mg & 800mg tablets.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>50.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>51.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Eslicarbazepine acetate
• Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs have been submitted.</td></tr>
<tr><td>52.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for Esli 200mg tablets & Esli 800mg tablet along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>53.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Eslicarbazepine acetate from API manufacturer for both Accelerated (40°C ± 2°C / 75% ± 5%RH) 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 48 months only.</td></tr>
<tr><td>54.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Esli tablets.</td></tr>
<tr><td>55.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet and also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>56.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted F2 factor protocol & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Esli 200mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 200mg tablet</td><td>Esli 200mg tablet</td></tr>
<tr><td>Batch No.</td><td>ZBCB</td><td>ESL-289210-2</td></tr>
<tr><th colspan="3">Esli 800mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Aptiom 800mg tablet</td><td>Esli 800mg tablet</td></tr>
<tr><td>Batch No.</td><td>PXFZ</td><td>ESL-290111-5</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
g. pH 1.2 HCl buffer
h. pH 4.5 Acetate buffer
i. pH 6.8 Phosphate buffer
• As per submitted reports both reference and trial product are comparable as with acceptable f2 value.
• Firm has submitted UV spectrums and raw data sheets for the CDP study.</td></tr>
<tr><td>57.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
</table>

Remarks of Evaluator[II]:	
Decision: Registration Board decided to approve registration of "Esli 800mg Tablets (Eslicarbazepine Acetate) and Esli 200mg Tablets (Eslicarbazepine Acetate) M/s Hilton Pharma (Pvt.) Ltd. 13, Sector 15, Korangi, Industrial Area, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.	

2266.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 90mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…….90mg"
	Diary No. Date of R& I & fee	Dy. No 1243 dated 10-01-2019, Rs.20,000/- Dated 10-01-2019
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance
	Remarks of the Evaluator[II]	

2267.	**Name and address of manufacturer / Applicant**	**"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"**
	Brand Name +Dosage Form + Strength	Tri-Plat Tablets 60mg
	Composition	"Each Film Coated Tablet Contains: Ticagrelor……60mg"
	Diary No. Date of R& I & fee	Dy. No 1639 dated 27-08-2013, Rs.50,000/- Dated 27-08-2013
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report dated 24-01-2018 concluded good level of cGMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA	
Drug	Tri-Plat Tablets 60mg
Name of Manufacturer	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1, SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India.
API Lot No.	8281034.
Description of Pack (Container closure system)	Alu-Alu blister in unit carton

Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH	
Time Period	Accelerated: 6 months Real Time: 6 months	
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6 (Months)	
Product	Trip-Lat 60mg	Trip-Lat 90mg
Batch#	Trial#01, Trial#02, Trial#03	Trial#01, Trial#02, Trial#03
Batch Size	1500 Tablets	1500 Tablets
Manufacturing Date	05-2019	06-2019

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Trip-Lat 60mg & 90mg tablets and provided the following documents in conjunction with the checklist approved by the Registration Board.

29.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection reports of their product "Saferon tablets (Sofosbuvir 400 mg)", which was presented in 278th meeting of Registration Board held on 29-31st Jan, 2018 **Observations:** Panel has observed that firm has improved as follows: • Floor has been renovated and painted with epoxy paint (anti-bacterial). • Old windows were replaced with double glazed windows. • Special Aluminium fixtures with rounded edges were installed. • Upgraded HVAC with pressure differentials was provided. • Firm has 06 tablet compression machines with capability of producing double layered tablets. Keeping in view improvements made by the firm as identified in the previous inspection, panel recommends the facilities of the firm for manufacturing of Saferon (Sofosbuvir 400mg) tablets and give rating of very Good. **Decision:** Registration Board decided to approve registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
30.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Submitted
31.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
32.	Stability study data of API from API manufacturer	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65%±5%RH) stability studies reports of three batches.
33.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 19011176) for M/s Glenmark Pharmaceuticals Ltd., Plot no., Z/103/1,SEZ Phase-II, Dahej, Taluka Vagra, Dist. Bhanch, 392130, Gujarat, India issued by Food & Drug Control Administration, Gujarat State, valid upto 08-08-2021.
34.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted following. •Commercial invoice attested by AD (I&E) DRAP, Islamabad dated 22-10-2018, Islamabad confirming import of Ticagrelor

<table>
<tr><td></td><td></td><td>(1.125Kg), Batch# 8281034.</td></tr>
<tr><td>35.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Firm has submitted authorized protocols for the development of Trip-Lat Tablets.</td></tr>
<tr><td>36.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>37.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has referred to the formulation of innovator product for establishing drug-excipient compatibility.</td></tr>
<tr><td>38.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided Batch Manufacturing Record for all the three batches.
<table>
<tr><th colspan="3">Tri-Plat 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>05-2019</td><td>1500 Tablets</td></tr>
<tr><th colspan="3">Tri-Plat 90mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>06-2019</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>06-2019</td><td>1500 Tablets</td></tr>
</table></td></tr>
<tr><td>39.</td><td>Record of comparative dissolution data (where applicable)</td><td>• Firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Phosphate Buffer) pH 6.8 buffers against reference product Brilinta tablet for both strengths concluding f2 value within acceptable limit.</td></tr>
<tr><td>40.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>41.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for HPLC analysis for all the three batches of Trip-Lat 60mg & 90mg tablets</td></tr>
<tr><td>42.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator[II]:
• Submitted batch manufacturing record declare use of 3% overage of API.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Tri-Plat Tablets 60mg (Ticagrelor) and Tri-Plat Tablets 90mg (Ticagrelor) by M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IV-A conditions.</td></tr>
</table>

Case no. 07 Applications on Form 5F

2268.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28339: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…60mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
API Lot No.	RD-TG- 201810081
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision:

3.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.

	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28340: 27-12-209
	Details of fee submitted	PKR 50,000/-: 27-12-2019
	The proposed proprietary name / brand name	**Taglor 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors (B01AC)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.

STABILITY STUDY DATA	
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China
API Lot No.	RD-TG- 201810081
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid Up to 31-12-2020.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. CYI18311) attested by DRAP Karachi office dated specifying import of Ticagrelor (2Kg) of batch# RD-TG- 201810081.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Observation	Firm's response
Justify the dissolution specification NLT 80%(Q) after 45 minutes, since the	• As per USFDA guidelines *"dissolution testing of Immediate release solid oral*

USFDA chemistry review document of the innovator product specify dissolution testing at two points i.e. NLT (Q) at 45 minutes and NLT (Q) at 60 minutes. • USFDA guidelines "dissolution testing of Immediate release solid oral dosage form" recommends that for slowly dissolving or poorly water soluble drugs, a two point dissolution specification, one at earlier time to include a dissolution range (a dissolution window) and the other at a later point (30, 45 or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product. The innovator product has also used the same approach and selected two time points for dissolution, justify how your finished product specification without a test for measure of dissolution range at 45 minutes & at 60 minutes to ensure 85% drug release be considered similar to that if innovator product. If your product shows more than 85% release in 45 minutes, how it can be considered similar with innovator product in terms of drug release	*dosage form"* Two time point dissolution analysis is recommended for development studies of BCS class II drugs and after development the final dissolution specifications will be set while the Ticagrelor falls in BCS class IV and many pharmacopeal monograph of BCS class IV and II available in pharmacopeia having only one time interval for dissolution test i.e. Clarithromycin , Leflunomide - • Furthermore, According to FDA chemistry review, the agency recommend the applicant (Innovator) to submit a supplement to set the final acceptance criteria for dissolution testing. • It is also mentioned in FDA reviews of Innovator data that the product shows consistent results at 45 minutes and the agency recommend to revised the proposed dissolution • To ensure the release pattern of SAMI product same as Innovator product, Comparative dissolution against innovator at different time point (i-e 45 and 60 minutes) has been performed and both products achieve the dissolution more than 80%(Q) after 45 minutes.**)** • We have also done testing at both time intervals i.e. 45 & 60 minutes at 9th month stability study at long term on stability batches • On the basis of above we have set the specification for dissolution i-e NLT 80% (Q) at 45 minutes.

Decision: Registration Board deferred the applications of Taglor 60mg Tablet & Taglor 90mg tablet and directed the firm to submit dissolution testing data with time pints of 45 minutes & 60 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

2269.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"**
	Name, address of Manufacturing site.	"M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2207: 21-02-2020
	Details of fee submitted	PKR 20,000/-: 18-02-2020
	The proposed proprietary name / brand name	**D-3 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each ml Contains: Cholecalciferol…….5mg"
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Vitamin D (A11CC05)
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1ml x 1's, 1ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by ANSM of France
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharmaceuticals (Reg.#063450)
	GMP Status of FPP manufacturer	GMP certificate issued on the basis of inspection conducted on 28-11-2019.
	Name and address of API manufacturer.	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Product:	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions of Zone-IVa.
	Pharmaceutical Equivalence	Firm has submitted comparison analysis studies against the reference product of Bouchara Recordati France.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data for the assay test performed by UV spectrophotometer.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India
API Lot No.	CLC0419019
Description of Pack (Container closure system)	1 ml clear glass ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml	TR-1/Vit D 5mg/ml
Batch Size	10000 Ampoules	10000 Ampoules	10000 Ampoules
Manufacturing Date	06-2019	06-2019	06-2019

Sr.#	Data required	Status
13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Canzin tablets", which was conducted on 14-03-2019, and was presented in 289th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail on testing reports is available.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Copy of GMP certificate (No. 181529) issued by the Jiangsu Drug Administration in the name of M/s Fermenta Biotech Ltd., India Plot no. Z-109, B& C, SEZ-II, Dahej, Tal-Vagra, City Dahej, Dist. Bharuch, Gujarat state, India has been submitted which was valid upto 02-01-2020.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (No. RV1002100166) attested by AD DRAP Karachi dated 09-04-2019, for import of 0.2Kg of Cholecalciferol (batch# CLC0419019)
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator^{II}:

- Firm has used 15% overage in the master formulation and submitted following justification for it:
  "Vitamin D3 is a heat sensitive material, when used as an active ingredient, cannot be terminally sterilized therefore subjected to filtration through microbial retentive materials. It is aseptically filled and sterilized by filtration by using 0.2um filter which have high chances of clogging and absorption. The assay limit is therefore set at 95% - 105% at the time of release, as API is lost during filtration process. Hence, 15% overage is used to compensate the process loss."
  Whereas, our result in accelerated stability are within the limit which justify the assay limit of 90% - 110% for shelf life. However, we undertake that we will revise our limit with 90% to 115% in finished product specification."
- Firm has applied UV method for the Assay analysis of drug product during stability studies.

Decision: Deferred for justification of performing Assay analysis of the drug product by UV spectrophotometric method.

2270.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"**
	Name, address of Manufacturing site.	"M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan"
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No28011: 23-12-2019
	Details of fee submitted	PKR 50,000/-: 23-12-2019
	The proposed proprietary name / brand name	**Etoxib tablet 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each film coated tablet contains: Etoricoxib …… 30mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	COX-2 inhibitor
	Reference to Finished product specifications	Manufacturer specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	Rs. 200/tablet
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	M/S Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP studies in three dissolution mediums has been submitted with acceptable level of f2 results.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, -Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India.
API Lot No.	84170527
Description of Pack	Alu-Alu blister in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	TF-051118	TF-061118	TF-071118
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	11-2018	11-2018	11-2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by the FDA Maharashtra India in the name of M/s Glenmark Pharmaceuticals Ltd. (India), Plot No. 141-143/160-165/170-172, Chandramouli Sahakari, Ayudyogik Vasahat, Maryadit, Pune, - Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India has been submitted which is valid upto 24-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Batch No.	Invoice No.	Quantity Imported.	Date of approval by DRAP
84170527	F2000002386	100Kg	01-03-2018

REMARKS OF EVALUATOR[II]:

Observation	Firm's response
Justification of 5% overage in the formulation(s) of stability batches shall be submitted since Overages are not acceptable unless fully justified.	This addition was not due to any specific reason, however we have reviewed the stability data of these three trial batches and noted that Assay & Dissolution results remain well within limits without significant change after 6 months accelerated stability.

	Furthermore we have evaluated that 5% overage impact on assay & Dissolution results and if we subtract 5% overage impact on assay & dissolution values, our values are still within limits. Furthermore we hereby commit that in commercial batch formulation of Etoxib tablet 30mg, overage will not be included.

Decision: Registration Board decided to approve registration of "Etoxib tablet 30mg (Etoricoxib) by M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

2271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals, S-95, SITE, Karachi.**
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23129: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 2.5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 2.5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted in 14-06-2018
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.

	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 2.5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20180205Y		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).

16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

2272.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Name, address of Manufacturing site.	Name: M/s Sami Pharmaceuticals, S-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23128: 08-11-2019
	Details of fee submitted	PKR 50,000/-: 08-011-2019
	The proposed proprietary name / brand name	**Xaby 5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban …… 5
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	10’s, 20’s, 30’s
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.

	Remarks of Evaluator: • Stability studies of drug substance as per Zone IVa conditions have been submitted.	
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative dissolution profile against the innovator's product i.e, Eliquis 5mg tablet and the results are within acceptable limit of f2 value.	

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., Ltd., China		
API Lot No.	20180205Y		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tabs.	2500 tabs.	2500 tabs.
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	01-2019	01-2019	01-2019
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empoli tablet 10mg & 25mg", which was conducted on 13-06-2019, and was presented in 290th meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked ✓ Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Manufacturing License for M/s Jiangxi Synergy, China issued by China Food & Drug Administration valid Up to 31-12-2020.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# JXS181027) cleared by DRAP Karachi office dated 01-02-2019 specifying import 0.13Kg Apixaban (Batch#20180205Y).

16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Decision: Registration Board decided to approve registration of "Xaby 2.5mg tablet (Apixaban) and Xaby 5mg tablet (Apixaban) by M/s Sami Pharmaceuticals, S-95, SITE, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

Item No. -: Agenda of Evaluator PEC-VIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs

c. New cases

2729.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …120mg"
	Diary No. Date of R& I & fee	Dy.No 9382 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	----
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	Applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2730.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etob 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib …60mg"
	Diary No. Date of R& I & fee	Dy.No 9380 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Starcox 60 mg tab by Getz Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved as per innovator's specification.	
2731.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox 500mg Tablets
	Composition	"Each dispersible contains: Deferasirox…500mg"
	Diary No. Date of R& I & fee	Dy.No 9378 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 500mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved as per innovator's specification.	
2732.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Defrox250mg Tablets
	Composition	"Each dispersible contains: Deferasirox…250mg"
	Diary No. Date of R& I & fee	Dy.No 9379 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3*10's , 2*14's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	

2733.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 100mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…100mg"
	Diary No. Date of R& I & fee	Dy.No 9374 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 100mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2734.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 200mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…200mg"
	Diary No. Date of R& I & fee	Dy.No 9375 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 200mg Tablet of Genix Pharma
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2735.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 1000mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…1000mg"
	Diary No. Date of R& I & fee	Dy.No 9362 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicia 1000mg Tablet of Martin Dow
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2736.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 750mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…750mg"
	Diary No. Date of R& I & fee	Dy.No 9361 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Vetrawin Tablets 750mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2737.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Etira Tablets 500mg
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…500mg"
	Diary No. Date of R& I & fee	Dy.No 9360 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Vetrawin Tablets 500mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2738.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Danon Tablets 4mg

	Composition	"Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…4mg"
	Diary No. Date of R& I & fee	Dy.No 9376 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zofran tablet 4mg of Glaxo welcome
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2739.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Serna Tablets 100mg
	Composition	"Each Film Coated Tablet Contains: Sertraline (as hydrochloride)…100mg"
	Diary No. Date of R& I & fee	Dy.No 9370 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	SSRIs
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Saytral 100mg Tablets of Sayyed Pharmaceuticals
	GMP status	GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator [VIII]	
	Decision: Approved.	
2740.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Grezon 90mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ticagrelor…90mg"
	Diary No. Date of R& I & fee	Dy.No 9986 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019

	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2741.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 145mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…145mcg"
	Diary No. Date of R& I & fee	Dy.No 9978 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2742.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 72mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…72mcg"
	Diary No. Date of R& I & fee	Dy.No 9977 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019

	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2743.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Clozon 290mcg Capsule
	Composition	"Each Capsule Contains: Linaclotide…290mcg"
	Diary No. Date of R& I & fee	Dy.No 9979 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Submit latest GMP inspection report
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2744.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Luzon 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lurasidone (ashydrochloride)…40mg"
	Diary No. Date of R& I & fee	Dy.No 9980 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(uncoated)Latuda (ema film)
	Me-too status	-----

	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required. • Reference Product is approved as uncoated tablet which is different from applied formulation submit either composition & master formulation after correction alongwith submission of requisite fee or evidence of reference product approved as film coated tablet.
	Decision: Deferred for the following: • **Submit either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **Submit either composition & master formulation after correction along with submission of requisite fee as reference product is approved as uncoated tablet or otherwise evidence of reference product approved as film coated tablet.**	
2745.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 12.5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9972 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (JARDIAMET 12.5 mg/850 mg)
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2746.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Empazin Plus 5/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…850mg"
	Diary No. Date of R& I & fee	Dy.No 9973 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA JARDIAMET 5 mg/850 mg
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2747.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Linazin Tablet 25/5mg
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No. 9969 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	7's,14's,28's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Glyxambi25 mg/5 mg tablets)
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.
	Decision: Deferred for the following: • **Submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.** • **For opinion of Legal Affairs Division regarding linagliptin for its patent rights.**	
2748.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Bimzin Eye Dop 0.3mg/ml
	Composition	"Each ml contains: Bimatoprost…0.3mg"
	Diary No. Date of R& I & fee	Dy.No 9966 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Anti-glaucoma
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications

	Pack size & Demanded Price	15ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (solution) (LUMIGAN: 0.03% **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Lumigan eye Drops of Barret Hodgson
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2749.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Detozin Injection 2ml
	Composition	"Each 2ml ampoule contains: Dexketoprofentrometamol 73.80mgeq to Dexketoprofen…50mg"
	Diary No. Date of R& I & fee	Dy.No 9967 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	5's,10's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.
	Decision: deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
2750.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"

	Brand Name +Dosage Form + Strength	TimprostOpthalmic Solution 50mcg/5mg
	Composition	"Each ml contains: Latanoprost…50mcg Timolol(as maleate)…5mg"
	Diary No. Date of R& I & fee	Dy.No 9976 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Prostaglandin analogue, antiglaucoma drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	2.5ml:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (solution)
	Me-too status	Latlol eye drops of Genix
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2751.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Dilatic Tablet 500mcg
	Composition	"Each Film Coated Tablet Contains: Roflumilast…500mcg"
	Diary No. Date of R& I & fee	Dy.No 10673 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Phosphodiesterase-4 (PDE-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30,s:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	• Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2752.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nepawal 1mg/1ml Opthalmic Solution
	Composition	"Each ml of opthalmic suspension contains: Nepafenac…1mg"
	Diary No. Date of R& I & fee	Dy.No 10672 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	3ml, 5ml(LDPE bottle):As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(suspension)
	Me-too status	Venac 0.1% of Vega Pharma
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	Please mention method used for sterilization of applied drug product.
	Decision: Deferred for submission of method used for sterilization of applied formulation.	
2753.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Artazon3ml Injection
	Composition	"Each ml contains: Atracurium besilate…10mg"
	Diary No. Date of R& I & fee	Dy.No 10615 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Nondepolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's,10's :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Elicurium injection 10mg/ml of Elite Pharma (2.5ml)
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator [VIII]	*MHRA 2.5 ml: Type I glass ampoule in packs of 5 ampoules. 5 ml: Type I glass ampoule in packs of 5 ampoules. 25 ml: Type I glass vial with rubber stopper in packs of 1 vial. • Evidence of approval of applied formulation in applied volume i.e. 3ml in reference agencies. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Submit Me Too in applied volume.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting in applied volume i.e 3ml.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in applied volume i.e 3ml..**	
2754.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan"
	Brand Name +Dosage Form + Strength	Nevazon 5/80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…5mg Valsartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 10674 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	beta blocker/ angiotensin receptor antagonist

	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's,20's,30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	-----
	GMP status	GMP Certificate issued on the basis of GMP inspection conducted on 1-03- 2019
	Remarks of the Evaluator VIII	Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is subsequent drug generic version.	
2755.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Topet Tablets 50mg
	Composition	"Each Film Coated Tablet Contains: Topiramate…50mg"
	Diary No. Date of R& I & fee	Dy.No 9373 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tics 50mg Tablet of Genix Pharma
	GMP status	Dated: 26-04-2019 GMP certificate is issued to the firm based on inspection conducted on 19-09- 2019.
	Remarks of the Evaluator VIII	
	Decision: Approved.	
2756.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Nitaxid 100mg/5ml Dry Suspension
	Composition	"Each 5ml Suspension after Reconstitution Contains: Nitazoxanide…100mg"
	Diary No. Date of R&I & fee	Dy.No 40911 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	30ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Nitox 100mg /5ml of M/s Regal Pharmaceuticals,
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 25. General Tablet Section

		26. General Capsule Section 27. Oral Dry Powder Suspension Section(General) 28. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2757.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Diclowin 50mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg" (core, enteric coating)
	Diary No. Date of R&I & fee	Dy.No 40927 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Dicmaf 50mg Tablet of Mafins
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 29. General Tablet Section 30. General Capsule Section 31. Oral Dry Powder Suspension Section(General) 32. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2758.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Serat 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline as hydrochloride…50mg"
	Diary No. Date of R&I & fee	Dy.No 40932 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Saytral 50mg Tablets of Sayyed Pharmaceuticals
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 33. General Tablet Section

		34. General Capsule Section 35. Oral Dry Powder Suspension Section(General) 36. Liquid Syrup(General)
	Remarks of Evaluator	
	Decision: Approved.	
2759.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Eprijen 50mg Tablet
	Composition	"Each sugar coated tablet contains: Eperisone HCL…50mg"
	Diary No. Date of R& I & fee	Dy.No 39902 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in PMDA
	Me-too status	Feloni 50mg Tablet of Hirani Pharmaceutical,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2760.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Rolajen 500mg XR Tablets
	Composition	"Each extended release tablet contains: Ranolazine …500mg"
	Diary No. Date of R& I & fee	Dy.No 40848 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	cardiac preparations
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)TGA
	Me-too status	Ranagin XR 500mg of Hilton Pharma
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit manufacturing method for relevant formulation as submitted method is of film coated tablet.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product.	
2761.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	"Jenfine Tablets 125mg
	Composition	"Each Tablet Contains: Terbinafine(as HCL)…125mg
	Diary No. Date of R& I & fee	Dy.No 39905 dated 04-12-2018 Rs.20,000/-

	Pharmacological Group	Antifunga
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA& TGA
	Me-too status	Logirid Tablet 125mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision:Approved.	
2762.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Setrom 8mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ondansetron dihydrate eq to Ondansetron …8mg"
	Diary No. Date of R& I & fee	Dy.No 40296 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Zofran Tablets 8mg of Glaxo Wellcome Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
2763.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Histajen 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ebastine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40843 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Desid Tablets 10mg ofGillman Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
2764.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura

	Brand Name +Dosage Form + Strength	Jen-Heim Tablet
	Composition	"Each chewable tablet contains: Iron III Hydroxide polymaltose complex eq to elemental iron…100mg Folic Acid…0.35mg"
	Diary No. Date of R& I & fee	Dy.No 40852 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	RBC-F tablets by Genix
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2765.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenprox SR Tablets 12.5mg
	Composition	"Each SR Tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 39906 dated 04-12-2018 Rs.20,000/
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Panox CR Tablet 12.5 mg of M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant & in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for submission of manufacturing method for relevant formulation and in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 12.5 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2766.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jentadin Tablets 5mg
	Composition	"Each Film Coated Tablet Contains: Desloratadine…5mg"
	Diary No. Date of R& I & fee	Dy.No 39907 dated 04-12-2018 Rs.20,000/-

	Pharmacological Group	ANTIHISTAMINES
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2767.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Piracet 800mg Tablets
	Composition	"Each Film Coated Tablet Contains: Piracetam…800mg"
	Diary No. Date of R& I & fee	Dy.No 39901 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Troopil Tablets 800 mg of ParamountPharmaceuticals,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	.
	Decision: Approved as per innovator's specification.	
2768.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Hiace5mg Tablet
	Composition	"Each uncoated tablet contains: Ramipril…5mg"
	Diary No. Date of R& I & fee	Dy.No 41393 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Ramy 5mg Tablet of Getz Pharma Karachi
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.

	Remarks of the Evaluator.	
	Decision: Approved with USP specifications	
2769.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Diora 50mg Capsule
	Composition	"Each Capsule Contains: Diacerin…50mg"
	Diary No. Date of R& I & fee	Dy.No 41392 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-osteoarthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Dorsett 50mg Capsule of Weather Folds Pharmaceuticals,
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2770.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Renavel 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sevelamer as HCL…400mg"
	Diary No. Date of R& I & fee	Dy.No 41391 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Foseal-800 Tablets Of M/S. Sncura Enterprises
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	Reference product is "Each Film Coated Tablet Contains: Sevelamer HCL…400mg"
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition:	

	"Each Film Coated Tablet Contains: Sevelamer HCL…400mg"	
2771.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Cande 16mg Tablet
	Composition	"Each uncoated tablet contains: Candesartan Cilexetil …16mg"
	Diary No. Date of R& I & fee	Dy.No 41408 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Miscand 16mg Tablet of Mission Pharma.
	GMP status	Dated: 23-02-2018 & 26-02-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satosfactry level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	On fee challan strength of tablet is 160 instead of 16.
	Decision: Approved as applied formulation is not available in strength of 160mg.	
2772.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Doxy Tablets 400mg
	Composition	"Each Film Coated Tablet Contains: Doxofylline…400mg"
	Diary No. Date of R& I & fee	Dy.No 40291 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Applied formulation is SR while manufacturing method is for enteric coated, submit the relevant.
	Decision: Deferred for submission of manufacturing method for relevant formulation in line with reference product.	
2773.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Ferriject 500mg/10ml Injection
	Composition	Each 10ml Ampoule Contains: Iron as ferric carboxymaltose…500mg

	Diary No. Date of R& I & fee	Dy.No 40162 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA (vial)
	Me-too status	Ferinject Injectable.Each 10ml vial contains:- Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2774.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Isofer 1000mg Injection
	Composition	"Each 10 ml Ampoule Contains: Iron as Iron III Isomaltoside…1000mg"
	Diary No. Date of R& I & fee	Dy.No. 40158 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2775.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	C-Cox 200mg Capsule
	Composition	"Each Capsule Contains: Celecoxib…200mg"
	Diary No. Date of R& I & fee	Dy.No 41057 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's,20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM

	Me-too status	Selxib -200mg Capsule OF M/s Fynk Pharmaceuticals,
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2776.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Rotcam 20mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Piroxicam…20mg"
	Diary No. Date of R& I & fee	Dy.No 40178 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m route)
	Me-too status	Piroxinor 20mg Injection ofM/s Nortech Pharmaceuticals, Pvt. Ltd
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2777.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden-Plus 75/20 mg Injection
	Composition	Each 2ml Ampoule Contains: Diclofenac Sodium…75mg Lidocaine Hydrochloride…20mg
	Diary No. Date of R& I & fee	Dy.No 40177 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID, Local anesthetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	2ml (10's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Swiss medic Diclofenac Mepha Injection by Mepha Pharm
	Me-too status	Lidoran of Danas Pharma
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	

2778.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Volden 75mg/3ml Injection
	Composition	"Each 3ml Ampoule Contains: Diclofenac Sodium…75mg"
	Diary No. Date of R& I & fee	Dy.No 40222 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3ml (5's): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM(i.m) but status is repealed.
	Me-too status	V-REN Liquid injection of M/s Regal Pharmaceuticals
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Submit justification on scientific basis for not performing terminal sterilization. Mention type of primary packaging material.
	Decision: Deferred for the following: • **Submit justification on scientific basis for not performing terminal sterilization.** • **Mention type of primary packaging material.**	
2779.	Name and address of manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Megatron Plus Syrup
	Composition	Each 5ml Contains: Iron III Hydroxide polymaltose complex…50mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy.No 41132 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Heamatinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	60ml : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2780.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No 41738 dated 07-12-2018 Rs.20,000/-

	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	14'sAs per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Barclor 250mg Tablet of Brand, Karachi .
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2781.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxflex Tablets 550mg
	Composition	Each film coated Tablet Contains: Naproxen Sodium…550mg
	Diary No. Date of R& I & fee	Dy.No 41727 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Freshnap Tablet 550mg of M/s Fresh Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2782.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxzole Tablets 500/400mg
	Composition	Each Tablet Contains: Diloxanide furoate…500mg Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy.No 41740 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-amoebic infection
	Type of Form	Form-5

	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	15's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(as provide by firm) (not verifiable)
	Me-too status	Dizet DS Tablets of M/s Rasco Pharma
	GMP status	Dated: 26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Clarification regarding salt of metronidazole is required.
	Decision: Deferred for clarification regarding salt form of API "Metronidazole" in applied formulation.	
2783.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dicmax Tablets 50mg
	Composition	Each film coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 41728 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Pngo 50mg Tablet of M/s Innvotek Pharmaceuticals
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2784.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 100mg
	Composition	Each Tablet Contains: Atenolol……..…100mg
	Diary No. Date of R& I & fee	Dy.No 41736 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	Me-too status	Atenocard Tablets 100mg of Fassgen Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2785.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxnol Tablets 50mg
	Composition	Each Tablet Contains: Atenolol…50mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Beta bloker
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Atenocard Tablets 50mg of Fassgen Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation; the firm the advice to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit Form 5 with correct strength & master formulation as it contains ingredients of coating but reference product is uncoated.
	Decision: Deferred for revision of formulation as per reference product.	
2786.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Famoday Tablet 20mg
	Composition	Each Film coated Tablet Contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy.No 41735 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's: As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Link-Live 20mg Tablet of Umema Pharma
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2787.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxtilium Tablets 10mg
	Composition	Each Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 41726 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Epodom 10mg Tablets of Atlantic Pharmaceutical
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
2788.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fucimax Cream 2%/1%
	Composition	Each tube contains: Fusidic Acid…2% Hydrocortisone…1%
	Diary No. Date of R& I & fee	Dy.No 41733 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anti- inflamatory
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	15gm: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (emc)
	Me-too status	Ucid-HC Cream of Ciba Pharmaceuticals,
	GMP status	Dated: 26-06-2019 **Conclusion:**

		The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advised to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Submit label claim of applied formulation in line with reference. Clarification regarding salt form of Hydrocortisone is required. Evidence of section approval.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference.** • **Clarification regarding salt form of Hydrocortisone is required.** • **Evidence of required manufacturing facility i.e., Cream/ ointment section from licensing is required.**	
2789.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Maxsec Tablets
	Composition	Each Tablet Contains: Amlodipine besylate…5mg
	Diary No. Date of R& I & fee	Dy. No 41737 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	Reference product contains Amlodipine as besylate…5mg
	Decision: approved with USP specifications and in line with reference product with following composition: **"Each Tablet Contains:** **Amlodipine as besylate…5mg "**	
2790.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarimax Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No 41739 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision:Approved.	
2791.	Name and address of manufacturer / Applicant	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenmax Tablets 100mg
	Composition	Each film coated Tablet Contains: Diclofenac sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 41730 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed in film coating(enteric coated is available)
	GMP status	Dated: 26-06-2019 **Conclusion:** The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2792.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 5mg Tablet

	Composition	"Each Tablet Contains: Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9094 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 5 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as "amlodipine as besylate 5mg tablet", submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition: "Each Tablet Contains: Amlodipine as besylate…5mg "	
2793.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi""
	Brand Name + Dosage Form + Strength	Pinex 10mg Tablet
	Composition	"Each Tablet Contains: Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9095 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Dipsan 10 mg Tablet of Sante Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as amlodipine as besilate 10mg tablet, submit composition/lable claim of applied formulation in line with reference product.
	Decision: Approved with USP specifications and in line with reference product with following composition: "Each Tablet Contains: Amlodipine as besylate…10mg "	
2794.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9049 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019

	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 5/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet.** **Updated status of GMP from QA & LT Division.**	
2795.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 10mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 9048 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 10/160/25mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 10mg, Valsartan 160mg, Hydrochlorothiazide 25mg in a tablet.** **Updated status of GMP from QA & LT Division**	
2796.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Coforge HCT Tablets 5mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine …5mg Valsartan…160mg Hydrochlorothiazide…12.5mg

	Diary No. Date of R&I & Fee	Dy.No 9047 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	As per SRO
	Me-too status	Aldric-H 5/160/12.5mg Tablet of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Deferred for the following: **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains amlodipine as besylate 5mg, Valsartan 160mg, Hydrochlorothiazide 12.5mg in a tablet.** **Updated status of GMP from QA & LT Division**	
2797.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/10mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…10mg
	Diary No. Date of R&I & Fee	Dy.No 6334 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…10mg "**	
2798.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 40mg/5mg

	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…40mg Amlodipine besylate…5mg
	Diary No. Date of R&I & Fee	Dy.No 6333 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 40/10mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…40mg** **Amlodipine as besylate…5mg "**	
2799.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Amelopin Tablet 20mg/5mg
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine besylate…5mg
	Diary No. Date of R&I & Fee	Dy.No 6335 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA/MHRA
	Me-too status	Baritec-A 20/5mg Tablet of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product.
	Decision: Registration Board decided to approve the applied formulation as per innovator's specifications and in line with reference product with following composition: **" Each Film Coated Tablet Contains:** **Olmesartan medoxomil…20mg** **Amlodipine as besylate…5mg "**	

2800.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/5mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9104 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating, submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2801.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine besylate…5mg"
	Diary No. Date of R&I & Fee	Dy.No 9103 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals

	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 5mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2802.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 40/10mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Amlodipine…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9105 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. • Master formulation contains ingredients of coating , submit the correct in line with reference product.MF contains ingredients of coating.
	Decision: **Deferred for the following:**	

	• **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2803.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amlotel Tablet 80/10mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Amlodipine besylate…10mg"
	Diary No. Date of R&I & Fee	Dy.No 9106 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine. Master formulation contains ingredients of coating , submit the correct in line with reference product.
	Decision: **Deferred for the following:** • **Submit composition of applied formulation in line with reference product as reference product contains Amlodipine as besylate 10mg and Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.** • **Master formulation contains ingredients of coating; submit the correct in line with reference product**.	
2804.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 5/40mg Tablets
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9063 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 5mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 40mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2805.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 10/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 9062 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following:	

	• **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 10mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2806.	Name and address of manufacturer / Applicant	"M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Amosart 5/80mg Tablets
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9064 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Reference product contains amlodipine as besylate 10mg in a tablet which is different from applied formulation. Submit composition of applied formulation in line with reference product. • Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: • **Mention salt form of API "amlodipine" in applied formulation along with submission of requisite fee as reference product contains Amlodipine as besylate 5mg, Telmisartan 80mg in a tablet.** • **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2807.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 8125 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA

	Me-too status	Telday Plus Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2808.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 10mg/40mg Tablet
	Composition	Each film coatedTablet Contains: Amlodipine as besylate…10mg Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 8124 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2809.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Telme S 5mg/80mg Tablet
	Composition	Each film coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 8126 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	10’s, 20’s, 30’s: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 5/80 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Please submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product along with submission of requisite fee and also submit evidence of tablet bilayer machine.**	
2810.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8173 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10’s, 14’s, 20’s, 28’s, 30’s, 60’s: Rs.600/-, Rs.840/-, Rs.1200/-, Rs.1680/-, Rs.1800/-, Rs.3600/-, As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2811.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8172 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO

	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2812.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8175 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2813.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/10mg
	Composition	Each tablet contains Telmisartan…40mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8174 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion:

		The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
2814.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Diary No. Date of R&I & Fee	Dy.No.5953 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Fenaso 10mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2815.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Solina Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5952 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Fenaso 5mg of M/s Highnoon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2816.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 2mg
	Composition	Each film coated tablet contains: Risperidone…2mg
	Diary No. Date of R&I & Fee	Dy.No 8182 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5

	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 2mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2817.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ripidon Tablet 4mg
	Composition	Each film coated tablet contains: Risperidone…4mg
	Diary No. Date of R&I & Fee	Dy.No 8183 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Becalm 4mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved	
2818.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 10mg
	Composition	Each film coated tablet contains: Rivaroxaban…10mg
	Diary No. Date of R&I & Fee	Dy.No 5957 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Xarelto 10 mg Tabs by Bayer
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2819.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 15mg
	Composition	Each film coated tablet contains: Rivaroxaban…15mg

	Diary No. Date of R&I & Fee	Dy.No 5958 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited,C/21, S.I.T.E.,Karachi."
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2820.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Roxaban Tablets 20mg
	Composition	Each film coated tablet contains: Rivaroxaban…20mg
	Diary No. Date of R&I & Fee	Dy.No 5959 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	factor Xa inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Rivox Tablet 20 mg of CSH, Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Mention isomeric form of rivaroxaban.(Innovator: S enantiomer)
	Decision: Approved with innovator's specifications.	
2821.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 5mg
	Composition	Each uncoated tablet contains: Aripiprazole…5mg
	Diary No. Date of R&I & Fee	Dy.No 5954 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Ariza 5mg Tablet of Hilton Pharma (Pvt.) Limited Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2822.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 10mg
	Composition	Each uncoated tablet contains: Aripiprazole…10mg
	Diary No. Date of R&I & Fee	Dy.No 5955 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 10mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2823.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Apriza Tablet 15mg
	Composition	Each uncoated tablet contains: Aripiprazole…15mg
	Diary No. Date of R&I & Fee	Dy.No 5956 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(orally disintegrating tablet)
	Me-too status	Arizo 15mg Tablet of S.J. & G. Fazul Ellahie (Pvt.) Ltd, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.
	Decision: Deferred for clarification regarding applied formulation whether it is orally disintegrating tablet or simply uncoated tablet is required.	
2824.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 6.25mg

	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R&I & Fee	Dy.No 6781 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Hidilol 6.25mg Tablets of Helix Pharma (Pvt.) Ltd; Karachi.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2825.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 12.5mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 6782 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 12.5mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2826.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Carvedo Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Carvedilol…25mg
	Diary No. Date of R&I & Fee	Dy.No 6783 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Cavidol 25mg Tablet of Indus Pharma, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	

2827.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Syrup 100mg/5ml(liq)
	Composition	Each 5ml of syrup contains: Doxofylline…100mg
	Diary No. Date of R&I & Fee	Dy.No 5944 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO
	Approval status of product in reference regulatory authorities	Doxofillina ABC 200 mg / 10 ml Syrup by M/s ABC Farmaceutici SpA –Corso Vittorio (Italian Medicine Agency (AIFA) Italy Approved)
	Me-too status	Profylline Syrup 100mg/ 5mlof Kaizen Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2828.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 500mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…500mg
	Diary No. Date of R&I & Fee	Dy.No 5947 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Ursochol 500 mg capsule, hard By Orifarm Generics A/S (Sweden Approved).
	Me-too status	Triptor Capsule 500mg of M/s CCL Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2829.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zoro Capsule 250mg
	Composition	Each hard gelatin capsule contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 5946 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Triptor Capsule 250mg of M/s CCL Pharmaceuticals

	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2830.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 16mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…16mg
	Diary No. Date of R&I & Fee	Dy.No 5951 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)
	Me-too status	Betoxen 16mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2831.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Beric Tablet 8mg
	Composition	Each uncoated tablet contains: Betahistine dihydrochloride…8mg
	Diary No. Date of R&I & Fee	Dy.No 5950 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti vertigo
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	3*10's: As per SRo
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)(uncoated)
	Me-too status	Betoxen 8mg Tablets of M/s. Pulse Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2832.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name + Dosage Form + Strength	Barlev Injection 500mg/5ml
	Composition	Each 5ml contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Eplipsa 500mg/5ml Injection of Helix Karachi .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Reference Product:*KEPPRA injection contains 100 mg of levetiracetam per mL. It is supplied in single-use 5 mL vials containing 500mg levetiracetam, water for injection, 45 mg sodium chloride, and buffered at approximately pH 5.5 with glacial acetic acid and 8.2 mg sodium acetate trihydrate. KEPPRA injection must be diluted prior to intravenous infusion. Mention type of primary packaging material.
	Decision: Deferred for submission of type of primary packaging material for applied formulation.	
2833.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Tamlev 100mg/ml oral Solution of Medisure Lab. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is solution you have applied for syrup, clarify.
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2834.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R&I & Fee	Dy.No 9040 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 250mg of M/s Akson Pharmaceuticals

	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2835.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Ikra 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R&I & Fee	Dy.No 9039 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	L-Epsi Tablet 500mg of M/s Akson Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2836.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 2.5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 5903 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2837.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…5mg
	Diary No. Date of R&I & Fee	Dy.No 5904 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2838.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Megacor 10mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…10mg
	Diary No. Date of R&I & Fee	Dy.No 5905 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:AS per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2839.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 10mg
	Composition	Each Tablet Contains: Bisoprolol…10mg
	Diary No. Date of R&I & Fee	Dy.No 9102 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 10mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.

	Remarks of the Evaluator	Reference product contains bisoprolol fumarate 10mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 10mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2840.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 2.5mg
	Composition	Each Tablet Contains: Bisoprolol…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 9100 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 2.5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 2.5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 2.5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2841.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Bisol tablet 5mg
	Composition	Each Tablet Contains: Bisoprolol…5mg salt?
	Diary No. Date of R&I & Fee	Dy.No 9101 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(film coated tablet)
	Me-too status	Bisfat Tablets 5mg of M/s. Dyson
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.

	Remarks of the Evaluator	Reference product contains bisoprolo fumarate 5mg, clarification regarding salt form of API is required.
	Decision: Deferred for the following: • **Mention salt form of API "bisoprolol" in applied formulation along with submission of requisite fee as reference product contains bisoprolol fumarate 5mg in a tablet.** • **Submit of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.**	
2842.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Vorizole Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R&I & Fee	Dy.No 6790 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta 1 blocker
	Type of Form	Form-5
	Finished product Specification	JP Specification
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc) (film coated)
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2843.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mislip Tablet 100mg
	Composition	Each uncoated tablet contains: Amisulpride…100mg
	Diary No. Date of R&I & Fee	Dy.No 6337 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Ampisol 100mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2844.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mislip Tablet 50mg
	Composition	Each uncoated tablet contains: Amisulpride…50mg

	Diary No. Date of R&I & Fee	Dy.No 6336 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti psychotic
	Type of Form	Form-5
	Finished product Specification	BP Specification
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Me-too status	Ampisol 50mg of Sami Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2845.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti-arthritis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board decided to approve registration of applied formulation for only hip and knee arthritis.	
2846.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Cancemos 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Capecitabine …500mg"
	Diary No. Date of R&I & Fee	Dy.No 4886 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Pyrimidine analogues
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	120's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Citabin 500mg tablet of m/s. Revive health care
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	

	Decision: Deferred for confirmation of manufacturing facility.	
2847.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Salmos Syrup 2mg/5ml
	Composition	Each 5ml contains: Salbutamol as sulphate…2mg
	Diary No. Date of R&I & Fee	Dy.No 5323 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Wintol syrup of Lisko
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	*MHRA: 100 ml, 150 ml and 200 ml type III amber glass bottle with Pilfer-Proof cap, screw cap or Child resistant closure. 100 ml and 150 ml HDPE bottle with screw cap, tamper evident cap or child resistant closure
	Decision: Approved as per innovator's specification.	
2848.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg Capsule
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 5325 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's,7's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fiscon capsule 50mg of Fassgen
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2849.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 200mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…200mg"

	Diary No. Date of R&I & Fee	Dy.No 5327 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's, 7's: As Per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Fcozole 200mg capsule of Medicraft
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2850.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 150mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…150mg"
	Diary No. Date of R&I & Fee	Dy.No 5326 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 4's, 7's,: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Flu-Z Capsule 150mg of Z-JANS Pharmaceuticals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
2851.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Mozole 50mg/5ml Suspension (DRY)
	Composition	Each 5ml contains: Fluconazole…50mg
	Diary No. Date of R&I & Fee	Dy.No 7274 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	35ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in MHRA(powder for oral suspension)
	Me-too status	Flucal of caliph pharmaceuticals
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferrred for confirmation of manufacturing facility i.e., "Dry powder suspension" section for applied formulation and revision of label claim.	

2852.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…50mg
	Diary No. Date of R&I & Fee	Dy.No 6784 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 50 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2853.	Name and address of manufacturer / Applicant	"M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Favox Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Fluvoxamine maleate…100mg
	Diary No. Date of R&I & Fee	Dy.No 6785 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ocedep 100 mg of Shaheen Pharmaceutical
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2854.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Velkeno 2.5mg/5ml Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R&I & Fee	Dy.No 5329 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	30ml, 60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Limited (Reg. #054519)
	GMP status	Dated:04-07-2018

		Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2855.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R&I & Fee	Dy.No 9050 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2856.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R&I & Fee	Dy.No 9051 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Sulpeol tablet of Danas Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2857.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Aliprid 100mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…100mg
	Diary No. Date of R&I & Fee	Dy.No 9052 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO

	Approval status of product in reference regulatory authorities	Approved in AIFA
	Me-too status	Lipride tablet 100mg of Polyfine chemicals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2858.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5330 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with reference
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2859.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Co-Telme 40mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 5331 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.

	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2860.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R&I & Fee	Dy.No 9065 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 20mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2861.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R&I & Fee	Dy.No 9066 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 40mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2862.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Temisart 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R&I & Fee	Dy.No 9067 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon tablets 80mg of Martin Dow
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2863.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 40/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9098 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence
	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2864.	Name and address of manufacturer / Applicant	"M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi"
	Brand Name + Dosage Form + Strength	Telmizide Tablet 80/12.5mg
	Composition	"Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & Fee	Dy.No 9099 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Velmon-H of Martin Dow
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is two-layered tablet. Please Submit manufacturing method in line with refrence

	Decision: Deferred for the following: **Submit either evidence of reference product approved as single layer tablet or otherwise revise formulation to bilayer tablet as per the reference product and also submit evidence of tablet bilayer machine.**	
2865.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Mefalgic 50mg/5ml Suspension
	Composition	Each 5ml contains: Mefenamic Acid…50mg
	Diary No. Date of R&I & Fee	Dy.No 5328 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 450ml: As per SSRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Constel 50mg/5ml suspension
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	MEntion type of primary packaging material Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Mention type of primary packaging material for applied formulation.**	
2866.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gesic 250mg Tablet
	Composition	Each Tablet Contains: Mefenamic Acid…250mg
	Diary No. Date of R&I & Fee	Dy.No 7306 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Genston of Genome Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Approval status of product in reference regulatory authorities?
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	

2867.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Secobal 500mcg Tablet
	Composition	Each Film Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R&I & Fee	Dy.No 5324 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's, 100's: as per SRO
	Approval status of product in reference regulatory authorities	PMDA Approved (but sugar coated)
	Me-too status	081876; Brand Name: Heam 500 mcg Tablet Manufacturer Name: Linear Parma,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for confirming film coating approval status in reference regulatory authorities.	
2868.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 600mg/2ml
	Composition	Each 2ml contains: Lincomycin as HCL…600mg
	Diary No. Date of R&I & Fee	Dy.No 5939 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	(2ml)::As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lincowrd 600mg Injection of Welwrd Pharmaceutical
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for justification on scientific grounds for not performing terminal sterilization of applied formulation.	
2869.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Lincostar Injection 300mg/ml

	Composition	Each ml contains: Lincomycin as HCL…300mg
	Diary No. Date of R&I & Fee	Dy.No 5938 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 5's, 10's(1ml): Rs.60/-, Rs.300/-, Rs.600/-, or as per SRO
	Approval status of product in reference regulatory authorities	Approved In USFDA***(could not be not confirmed in applied volume i.e. 1 ml)***
	Me-too status	Farcocine Injection of Farmaceutics Int. Karachi
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	Justification for not performing terminal sterilization is required.
	Decision: Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Deferred for evidence of approval of applied formulation in applied volume i.e. "1ml" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2870.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Doxylin Tablets 400mg
	Composition	Each uncoated tablet contains: Doxofylline…400mg
	Diary No. Date of R&I & Fee	Dy.No 5945 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved)
	Me-too status	Ofylin 400mg Tablet of S.J &G. Fazul Ellahie
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2871.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 300mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…300mg
	Diary No. Date of R&I & Fee	Dy.No 5949 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5

	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	20's, 30's: As per SRO
	Me-too status	
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…300mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2872.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Britain SR Tablet 150mg
	Composition	Each Film Coated sustained release Tablet Contains: Bupropion Hcl…150mg
	Diary No. Date of R&I & Fee	Dy.No 5948 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Butrin XL 150mg tablet of Genome
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Submit label claim of applied formulation in line with reference product. i.e. Each sustained release Tablet Contains: Bupropion Hcl…150mg
	Decision: Deferred for submission of Submit label claim/composition of applied formulation in line with reference product.	
2873.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R&I & Fee	Dy.No 5906 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexipin 200mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2874.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R&I & Fee	Dy.No 5907 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexfen 300mg tablet of Hygeia
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2875.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bravofen-DX 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R&I & Fee	Dy.No 5908 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:as per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM(but status is repealed)
	Me-too status	Dexipin 400mg tablet of AGP
	GMP status	Panel inspection conducted on 09-07-2018 recommended issuance of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2876.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Aronic Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Ibandronate Sodium Monohydrateequivalent to ibandronic acid…150mg
	Diary No. Date of R&I & Fee	Dy.No 5943 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	bisphosphonate
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	1's, 3's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA

	Me-too status	Boonset of Barret Hodgson
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2877.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Uro Trate Tablet 10meq
	Composition	Each extended release tablet contains: Potassium citrate…10meq
	Diary No. Date of R&I & Fee	Dy.No 5942 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	urinary alkalinizing agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,20's'30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Urocit-K 10meq Tablets Of Universal Enterprises
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2878.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Onvin Syrup 4mg
	Composition	Each 5ml contains: Ondansetron as Hcl dihydrate…4mg
	Diary No. Date of R&I & Fee	Dy. No 5941 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP specification
	Pack size & Demanded Price	50ml, 60ml,120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Not verifiable
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2879.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Valrate Oral Solution 250mg/5ml
	Composition	Each 5ml of oral syrup contains: Sodium valproate eq to valporic acid…250mg
	Diary No. Date of R&I & Fee	Dy. No 5940 dated 11-02-2019, Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	60ml, 120ml : As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dipodium of 250mg/5ml syrup of Lexicon
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Evidence of approval status of product in reference regulatory authorities is required. Clarification regarding physical form of applied drug product is required (syrup or solution?)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2880.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Baymil Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Bamifylline…600mg
	Diary No. Date of R&I & Fee	Dy.No 6780 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Bamiscot of scottmann
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.	
2881.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acerein Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein…50mg
	Diary No. Date of R&I & Fee	Dy.No 6332 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in ANSM
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per indications approved by reference regulatory authorities.	
2882.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Barresten HC Cream 10/10mg

	Composition	Each gram contains: Clotrimazole…10mg Hydrocortisone acetate eq to Hydrocortisone…10mg
	Diary No. Date of R&I & Fee	Dy.No 6718 dated 15-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiinfectives And Antiseptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Razole Cream of Ciba Pharmaceuticals, Karachi . .
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2883.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Nitazoxanide…500mg
	Diary No. Date of R&I & Fee	Dy.No 6788 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Izato 500mg tablet of Sami
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2884.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Nitazid Dry Powder Oral suspension 100mg/5ml
	Composition	Each 5ml contains when reconstituted: Nitazoxanide…100mg
	Diary No. Date of R&I & Fee	Dy.No 6789 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30ml, 60ml; As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nitranex 100mg/5ml of Nexus Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Approved.	
2885.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 40mg
	Composition	Each enteric Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…40mg
	Diary No. Date of R&I & Fee	Dy.No 6799 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	7's, 10's, 14's, 20's,28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Nexium tablets
	Me-too status	Zimol 40 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2886.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 40mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate e to Ziprasidone…40mg
	Diary No. Date of R&I & Fee	Dy.No 6796 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Zpras 40mg Capsule of Wellborne Pharmachem
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2887.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zitra Tablet 30mg
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R&I & Fee	Dy.No 6794 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	ANTIDEPRESSANTS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	20's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA

	Me-too status	Zepidep Tablet 30mg of Saydon Pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2888.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Torek Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg
	Diary No. Date of R&I & Fee	Dy.No 6793 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2889.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Pirament Syrup 1gm(liq)
	Composition	Each 5ml contains: Piracetam……1gm
	Diary No. Date of R&I & Fee	Dy.No 6786 dated 15-02-2019 Rs.20,000/-
	Pharmacological Group	N06BX: Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Greytone 1000mg/5ml suspension of High-Q
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2890.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Esomet Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Esomeprazole Magnesium trihydrate eq to Esomeprazole…20mg
	Diary No. Date of R&I & Fee	Dy.No 6798 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification

	Pack size & Demanded Price	7's, 10's,14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved MHRA
	Me-too status	Zimol 20 Tablets of pacific
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2891.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Zipiras Capsule 80mg
	Composition	Each Capsule Contains: Ziprasidone HCL Monohydrate eq. to Ziprasidone…80mg
	Diary No. Date of R&I & Fee	Dy.No 6797 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's,14's,20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ziprox 80mg Capsule of Nabiqasim Industries
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2892.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 30mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…30mg Source : Vision but stability is not submitted
	Diary No. Date of R&I & Fee	Dy.No 6792 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 30mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2893.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Benzarin SR Capsule 15mg
	Composition	Each Capsule Contains: Cyclobenzaprine hcl extended release pellets eq to Cyclobenzaprine…15mg Source : Vision but stability is not submitted

	Diary No. Date of R&I & Fee	Dy.No 6791 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cyclorest-ER 15mg of Martin Dow
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2894.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Quitapine ST Tablets 300mg
	Composition	Each extended release film coated tablet contains: Quetiapine fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 6795 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Inno Specification
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Qusel XR 300mg Tablet of Hilton Pharma Karachi . .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Quetiapine as fumarate…300mg extended release tablet.
	Decision: Deferred for submission of lable claim/composition of applied formulation in line with reference product i.e. Quetiapine as fumarate…300mg extended release tablet.	
2895.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Carbofer Injection 500mg/10ml
	Composition	Each 10ml ampoule contains: Iron as ferric carboxymaltose…500mg
	Diary No. Date of R&I & Fee	Dy.No 6977 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA (vial) Ferinject Injectable.Each 10ml vial contains:-
	Me-too status	Iron as ferric carboxymaltose 500mg of M/s. RG Pharmaceutica (Pvt.) Ltd.,
	GMP status	Dated: 16th-28th Aug, 2018.

		Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2896.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Drospa Fort Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Drotaverine HCL…80mg
	Diary No. Date of R&I & Fee	Dy.No 6961 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	antispasmodic drug
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in AIFA italy
	Me-too status	Relispa Forte Tablets of Searle Pakistan, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2897.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Actirin Capsule 25mg
	Composition	Each Capsule Contains: Acitretin…25MG
	Diary No. Date of R&I & Fee	Dy.No 6964 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	NEOTIGASON CAPSULE 25mg Of MULLER &PHIPPS KARACHI
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2898.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Acitirin Capsule 10mg
	Composition	Each Capsule Contains: Acitretin…10MG
	Diary No. Date of R&I & Fee	Dy.No 6963 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019

	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	7's, 10's, 14's,20's,28's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	ACT 10mg Capsule of Ciba Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2899.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 100mg
	Composition	Each uncoated tablet contains: Clozapine…100mg
	Diary No. Date of R&I & Fee	Dy.No 6760 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's,50's, 60's : As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ekloz 100 mg Tablets of WnsFeild Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2900.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Capsule 40mg
	Composition	Each Capsule Contains: Omeprazole as enteric coated pellets, 8.5%...40mg Source: Vision
	Diary No. Date of R&I & Fee	Dy.No 6956 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2901.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fymezole Insta Plus Sachet

	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R&I & Fee	Dy.No 7534 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Ruling + Sachet of High-Q,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2902.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 500mg/ml
	Composition	Each ml contains: Cefpirome Sulfate …500mg
	Diary No. Date of R&I & Fee	Dy.No 8469 dated 26-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	CEFROM INJECTION 0.5GM of HOECHST MARION ROUSSEL KARACHI
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …0.5gm. Mention type of primary packaging material.
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	
2903.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Piro Mark Dry Powder Injection 1gm/ml
	Composition	Each ml contains: Cefpirome Sulfate …1gm
	Diary No. Date of R&I & Fee	Dy.No 8470 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	ANSM (France) By M/s Saofi Aventis France.
	Me-too status	Cefrom Injection 1gm by M/s Sanofi Aventis (Reg#021124)
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefpirome as sulfate …1gm
	Decision: Deferred for revision of formulation as per reference product alongwith details of primary packaging material.	

2904.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 1.5gm/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…1.5gm
	Diary No. Date of R&I & Fee	Dy.No 8442 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 1.5 g of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 1.5mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…1.5gm**	
2905.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 750mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…750mg
	Diary No. Date of R&I & Fee	Dy.No 8441 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 750 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 750mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…750mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…750mg**	
2906.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox Dry Powder Injection 250mg/vial
	Composition	Each Vial Contains: Cefuroxime Sodium…250mg
	Diary No. Date of R&I & Fee	Dy.No 8440 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Zinacef 250 mg of GSK Ltd., UK (MHRA)
	Me-too status	Rubect 250mg injection IV of Silver Oak
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product contains Cefuroxime as Sodium…250mg
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each Vial Contains:** **Cefuroxime (as sodium)…250mg**	
2907.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	M-Urox 125mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Cefuroxime Axetil…125mg
	Diary No. Date of R&I & Fee	Dy.No 8467 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml: As Per PRC
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Purox 125mg/5ml Dry Suspension of M/s ARP (Pvt) Ltd,
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML.
	Remarks of the Evaluator	Reference product is approved as Cefuroxime as axetil…125mg per 5ml suspension.
	Decision: Approved with USP Specifications with following composition in line with reference product: **Each 5ml contains:** **Cefuroxime (as axetil)…125mg**	
2908.	**Deleted: Duplication of Case No.2351**	
2909.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 3mg Tablet
	Composition	Each Tablet Contains: Paliperidone…3mg
	Diary No. Date of R&I & Fee	Dy.No 7276 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018

		Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2910.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 6mg Tablet
	Composition	Each Tablet Contains: Paliperidone…6mg
	Diary No. Date of R&I & Fee	Dy.No 7277 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 10's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved USFDA
	Me-too status	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2911.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Palidon 1.5mg Tablet
	Composition	Each Tablet Contains: Paliperidone…1.5mg
	Diary No. Date of R&I & Fee	Dy.No 7275 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1's, 14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Palitec XR 1.5mg Tablet of Pharmatec Karachi . .
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is produced by OROS Push Pull Technology.
	Decision: Deferred for submission of manufacturing outline of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2912.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cozipin Tablet 25mg

	Composition	Each uncoated tablet contains: Clozapine…25mg
	Diary No. Date of R&I & Fee	Dy.No 6959 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 50's, 60's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Amlepo 25mg Tablet of Amarant
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2913.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Itradex Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole…100mg (IR Pellets) Source: vision
	Diary No. Date of R&I & Fee	Dy.No 8188 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	4's, 8's, 12's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2914.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 67mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…67mg
	Diary No. Date of R&I & Fee	Dy.No 8185 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Corfibrate 67mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Approved.	
2915.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Detora Tablet 5mg
	Composition	Each film coated release tablet contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8184 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 20's, 100's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Lyon 5mg Tablets of Fassgen Pharmaceuticals,
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2916.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 4mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…4mg
	Diary No. Date of R&I & Fee	Dy.No 8129 dated 25-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs),
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Canex 4mg Tablets of Wellborne Pharmachem and Biologicals,
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2917.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Ilop 1mg Tablet
	Composition	Each Tablet Contains: Iloperidone …1mg

	Diary No. Date of R&I & Fee	Dy.No 7278 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIPSYCHOTICS
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	ILOPER 1mg Tablet of Hilton
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2918.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac C 32mg/25mg Tablet
	Composition	Each film coated Tablet Contains: Candesartan…32mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy. No 8130 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Advantec Tablet of Getz Pharma Karachi
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	
	Decision: Deferred for the following: **Mention salt form of API "Candesartan" in applied formulation along with submission of requisite fee in line with reference product.**	
2919.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 8mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…8mg
	Diary No. Date of R&I & Fee	Dy.No 8127 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 8mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018

		Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2920.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Setac 16mg Tablet
	Composition	Each film coatedTablet Contains: Candesartan cilexitil…16mg
	Diary No. Date of R&I & Fee	Dy.No 8128 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved n MHRA
	Me-too status	Miscand 16mg Tablet of Mission Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	Reference product is uncoated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2921.	Name and address of manufacturer / Applicant	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad
	Brand Name + Dosage Form + Strength	Mednir 250mg/5ml dry powder suspension
	Composition	Each 5ml contains: Cefdinir…250mg
	Diary No. Date of R&I & Fee	Dy.No 8474 dated 26-02-2019 Rs.20,000/- ated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	14's, 28's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Cefnir 250mg/5ml Dry Suspension of Barrett Hodgson Pakistan
	GMP status	Inspection date 16/10/2018, the panel recommended renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications.	
2922.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Viptin 50mg Tablet
	Composition	Each Tablet Contains: Vildagliptin…50mg
	Diary No. Date of R&I & Fee	Dy.No 7297 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Hypoglycemic
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Vilda 50mg of M/s. Rotex Pharma (Pvt) Ltd, Islamabad
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved as per innovator's specification.	
2923.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Lebirat Capsule 200mg
	Composition	Each Capsule Contains: Fenofibrate (Micronized)…200mg
	Diary No. Date of R&I & Fee	Dy.No 8186 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Corfibrate 200mg Capsule of OBS Karachi .
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2924.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ciricode syrup for oral soultion 100mg
	Composition	Each ml contains: Citicoline as Sodium…100mg
	Diary No. Date of R&I & Fee	Dy.No 6965 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	30ml, 60ml,120ml: As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Cercolin Syrup of M/s Schazoo Laboratories,

	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2925.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…20mg
	Diary No. Date of R&I & Fee	Dy.No 9058 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10,s: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2926.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Rosulip 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…40mg
	Diary No. Date of R&I & Fee	Dy.No 9059 dated 28-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Rosocard Tablets of M/s Himont
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2927.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 100mg Capsules
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R&I & Fee	Dy.No 9044 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO

	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 100mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2928.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 300mg Capsules
	Composition	Each Capsule Contains: Pregabalin…300mg
	Diary No. Date of R&I & Fee	Dy.No 9046 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Nurica 300mg Capsule of Macter Int. Karachi
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2929.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9075 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiinfectives and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)
	Me-too status	Robecide 200 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee.** **Updated status of GMP from QA & LT Division.**	
2930.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi

	Brand Name + Dosage Form + Strength	Amlogyl Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Metronidazole as benzoate…400mg
	Diary No. Date of R&I & Fee	Dy.No 9076 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(but without benzoate salt)
	Me-too status	Robecide 400 mg Tablets of Rock Pharmaceuticals Laboratories, (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or otherwise revise applied formulation in line with reference product without benzoate salt along with submission of requisite fee. **Updated status of GMP from QA & LT Division.**	
2931.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 400mg Tablet
	Composition	Each Tablet Contains: Linezolid…400mg
	Diary No. Date of R&I & Fee	Dy.No 9053 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(zyvox tablet 400mg) (but discontinued, however it is written that Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	Barizold tablet 400mg of Barrett Hodgson(Reg #076342)
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2932.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Inezon 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…600mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019

	Pharmacological Group	antibacterials
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	LinzolTablet 600 mg of M/s Regal Pharmaceuticals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Reference product is film coated tablet
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2933.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 75mg Capsules
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R&I & Fee	Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Regab of Caraway pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2934.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Azonax 0.25mg Tablet
	Composition	Each film coated Tablet Contains: Alprazolam…0.25mg
	Diary No. Date of R&I & Fee	Dy.No 9037 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Medilap 0.25mg Tablet of Wellborne Pharmachem and Biologicals,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for following: **Evidence of approval of required manufacturing facility "Tablet psychotropic section" from licensing division.** **Updated status of GMP from QA & LT Division.**	

2935.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 500mg Tablet
	Composition	Each Tablet Contains: Mebendazole…500mg
	Diary No. Date of R&I & Fee	Dy.No 9072 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	ANTINEMATODAL AGENTS
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Leukiban Tablets 100mg of Rakaposhi Pharmaceuticals (Pvt) Ltd.,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2936.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Viredo B Tablet 300mg
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil as Fumarate…300mg
	Diary No. Date of R&I & Fee	Dy.No 9061 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	
	Me-too status	
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2937.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Ikra Syrup 100mg/ml Suspension
	Composition	Each ml of syrup contains: Levetiracetam…100mg
	Diary No. Date of R&I & Fee	Dy.No 9041 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Levetiracetam Thame 100mg/ml Oral Solution
	Me-too status	Levefil Oral Solution of Pharmatec Karachi

	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2938.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Amlogyl Suspension 200mg/5ml
	Composition	Each 5ml of suspension contains: Metronidazole as benzoate…200mg
	Diary No. Date of R&I & Fee	Dy.No 9074 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti-infective and antiseptics for local oral treatment
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Mogel 200mg Suspension of M/s Metro Pharmaceuticals
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2939.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabreg 50mg Capsules
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R&I & Fee	Dy.No 9042 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	antiepileptic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Dygab 25mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP from QA & LT Division.	
2940.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 50mg Tablet
	Composition	Each Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but outline of method of manufacturing do not contain step of coating.	
2941.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Clossium 75mg Tablet
	Composition	Each film coated Tablet Contains: Diclofenac potassium…75mg
	Diary No. Date of R&I & Fee	Dy.No 7302 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.	
2942.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lowstat 10mg Tablet
	Composition	Each Tablet Contains: Simvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 7304 dated 20-02-2019 Rs.20,000/-
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(film coated tablet)
	Me-too status	Mistin 10mg Tablet of Mission Pharma.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.

	Remarks of the Evaluator	Clarification regading coating of tablet is required as Master Formulation contains ingredients of coating but manufacturing method do not have step of coating.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2943.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hcl…10mg
	Diary No. Date of R&I & Fee	Dy.No 7296 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.	
2944.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 10mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…10mg
	Diary No. Date of R&I & Fee	Dy.No 9092 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Save-R Tablets 10mg of Wilson's Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…10mg film coated tablet.
	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 10mg in a tablet.**	

	• **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2945.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Lipinil 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…20mg
	Diary No. Date of R&I & Fee	Dy.No 9093 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Registration Number 080326 Brand Name Restore 20mg Tablet (Rosuvastatin calcium) Manufacturer Name Mission Kar. Manufacturer Address Karachi
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as Rosuvastatin as calcium trihydrate…20mg film coated tablet.
	Decision: Deferred for the following: • **Mention salt form of API "Rosuvastatin" in applied formulation along with submission of requisite fee as reference product contains Rosuvastatin as calcium trihydrate 20mg in a tablet.** • **Submit either evidence of reference product approved as uncoated tablet or otherwise revise formulation to film coated tablet as per the reference product along with submission of requisite fee.**	
2946.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Moxibax 400mg Tablet
	Composition	Each Tablet Contains: Moxifloxacin Hcl…400mg
	Diary No. Date of R&I & Fee	Dy.No 7309 dated 20-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA Avelox 400mg film-coated tablets byM/s Bayerplc,
	Me-too status	Molinza tablet 400mg M/S Zafa
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.

	Remarks of the Evaluator	Reference product is approved as Moxifloxacin as Hcl…400mg film coated tablet. Master Formulation contains ingredients of coating
	Decision: Deferred for the following: **Submission of Form 5, master formulation, manufacturing method after correction in line with reference product Moxifloxacin as Hcl 400mg film coated tablet.**	
2947.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Atenox Tablet 25mg
	Composition	Each Tablet Contains: Atenolol…25mg
	Diary No. Date of R&I & Fee	Dy.No 9096 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	BETA BLOCKING AGENTS
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA(uncoated tablet)
	Me-too status	Atomin 25mg Tablet of Semos Pharmaceuticals
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Master Formulation contains ingredients of coating
	Decision: Deferred for the following: **Submission of master formulation after correction in line with reference product Moxifloxacin as Hcl…….400mg film coated tablet.**	
2948.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Desodine 5mg Tablet
	Composition	Each film coated tablet Contains: Desloratadine…5mg
	Diary No. Date of R&I & Fee	Dy.No 9089 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Desolar Tablets 5mg of Bryon Pharma (Pvt.) Ltd.
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet. MF contains ingredients of coating
	Decision: Approved with innovator's specifications.	
2949.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Salazo-En 500mg Tablet

	Composition	Each Tablet Contains: Sulfasalazine…500mg
	Diary No. Date of R&I & Fee	Dy.No 7295 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in TGA
	Me-too status	Zalaz Tablets of Mediate Pharmaceutical
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as enteric coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Deferred for revision of formulation as per reference product alongiwth requisite fee.	
2950.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart Tablet 80mg
	Composition	Each Film coated tablet Contains: Valsartan…….80mg
	Diary No. Date of R&I & Fee	Dy.No 9091 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Valsartan 80mg Film-coated Tablets (MHRA Approved)
	Me-too status	Valseta 80mg Tablet by Maple Pharma (Reg#83347)
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	MF contains ingredients of coating.
	Decision: Approved .	
2951.	Name and address of manufacturer / Applicant	M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Nermox 100mg/5ml(dry)
	Composition	Each 5ml contains: Mebendazole…100mg
	Diary No. Date of R&I & Fee	Dy.No 9073 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antinematodal agents
	Type of Form	Form-5
	Finished product Specification	mfg Specification
	Pack size & Demanded Price	30ml: As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA (emc)
	Me-too status	Nemazole Suspension of M/s Nexus Pharma
	GMP status	GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator	
	Decision: Deferred for following: **Revision of formulation from dry suspension to liquid suspension alongwith submission of requisite fee.** **Updated status of GMP from QA & LT division.**	
2952.	Name and address of manufacturer / Applicant	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cetin 10mg Tablet
	Composition	Each Tablet Contains: Cetirizine Hydrochloride……..…10mg
	Diary No. Date of R&I & Fee	Dy.No 9090 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti histamine
	Type of Form	Form-5
	Finished product Specification	Mfg Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc) (film coated tablet)
	Me-too status	Concidol Neo Tablet of Convell Laboratories,
	GMP status	GMP inspection conducted on 10-10-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator	Reference product is approved as film coated tablet submit applied formulation either in line with reference product along with submission of requisite fee or evidence of reference product approved as uncoated tablet.
	Decision: Registration Board decided to reject the application as same formulation with same brand name is considered in the name of M/s Baxter Pharmaceuticals at serial No. 2387.	
2953.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Fyprox CR Tablet 25mg Fyprox CR Tablet 12.5mg
	Composition	Each enteric film coated tablet contains: Paroxetine as Hydrochloride……..…25mg
	Diary No. Date of R&I & Fee	Dy.No 7539 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Deroxat CR tablet 25mg by Global Pharma
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Submit composition/label claim of applied formulation in line with product approved in reference agencies i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.

	Decision: Deferred for submission of composition/label claim and manufacturing method for applied formulation in line with reference product i.e. each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 25 mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.	
2954.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Oltal F Capsule 3mg/25mg
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine HCL eq to Fluoxetine…25mg
	Diary No. Date of R&I & Fee	Dy.No 7540 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in reference regulatory authorities	Symbyax 3 mg/25 mg Capsules of Eli Lilly , USA (USFDA)
	Me-too status	Olanzo-F 3/25 mg Capsules of Regal pharmaceuticals
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2955.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Ploro T Injection 40mg/0.04mg
	Composition	Each 4ml ampoule contains: Pholoroglucinol hydrated…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R&I & Fee	Dy.No 7536 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	antispasmodic agent
	Type of Form	Form-5
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	(4ml) 6's: As per SRO
	Approval status of product in reference regulatory authorities	Phloroglucinol/Trimethylphloroglucinol Arrow 40 mg / 0.04 mg per 4 ml, solution for injection by M/s GENERIC ARROW, ANSM France
	Me-too status	Anafortan Plus Injection 40mg/0.04mg (4ml ampoule) by M/s Ali Gohar Pharmaceuticals (Pvt) Ltd, Reg. No. 24503
	GMP status	GMP inspection conducted on 21-11-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2956.	**Name and address of manufacturer / Applicant**	**"M/s Walt Danzay Pharmaceuticals. 35-A, Punjab, Small Industrial Estate,Taxila, Paksitan"**
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% Injection
	Composition	Sodium Chloride 0.9% Injection Each ml Ampoule Contains: Sodium Chloride…0.9%w/v"
	Diary No. Date of R& I & fee	Dy.No.21048 dated 12-06-2018 Rs.20,000/-
	Pharmacological Group	Diluent
	Type of Form	Form-5

	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's (5ml), (10ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Norsal 0.9% Infusion of Nabiqasim Industries
2957.	GMP status	
	Remarks of Evaluator	• Justification on scientific basis for addition of 3% overage in applied formulation. • Mention quantity of sodium chloride in one ml & submit master formulation accordingly. • Submit separate application for each applied volume. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility & Submit latest GMP inspection report.
	Decision: Registration Board decided to reject the application since DML in the name of M/s Walt Danzy Pharmaceuticals is not valid.	
2958.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Palidol 6mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…6mg"
	Diary No. Date of R& I & fee	Dy.No. 21235 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega6mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2959.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**
	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5

	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2960.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 5mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No. 21242 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO Rs.182/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nebilol 5mg Tablet of Genix Pharma Karachi
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2961.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson10mg Tablet
	Composition	Each film coated tablet Contains: Nebivolol (as hydrochloride)…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21243 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.300/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.

	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2962.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Tenson 2.5mg Tablet
	Composition	"Each film coated tablet Contains: Nebivolol (as hydrochloride)…2.5mg"
	Diary No. Date of R& I & fee	Dy.No. 21241 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's:As per SRO or Rs.108/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 2.5mg of M/s. Dyson Research Laboratories
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	Reference product in uncoated tablet but applied formulation is coated.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2963.	**Name and address of manufacturer / Applicant**	**"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"**
	Brand Name +Dosage Form + Strength	Diabet 50mg Tablet
	Composition	"Each Tablet Contains: Vildagliptin…50mg"
	Diary No. Date of R& I & fee	Dy.No. 21239 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	28's:As per SRO or Rs.1471.08/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Galvus Tablets 50mg Of Novartis Pharma
	GMP status	GMP Inspection conducted on 08-02-2018 concluded that the firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
2964.	**Name and address of manufacturer / Applicant**	**"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"**

	Brand Name +Dosage Form + Strength	Telsira 12.5/40 mg Tablet
	Composition	"Each Tablet Contains: Hydrochlorothiazide…12.5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No.21236 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Thiazide Diuretics,Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velmon-H 40/12.5mg of Martin Dow Ltd. Karachi.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.
	Decision: Deferred for submission of evidence of purchase of tablet bilayer machine involved in manufacturing of applied formulation.	
2965.	**Deleted: Duplication of case at Serial No. 2404**	
2966.	**Deleted: Duplication of case at Serial No. 2405**	
2967.	**Deleted: Duplication of case at Serial No. 2406**	
2968.	**Deleted: Duplication of case at Serial No. 2407**	
2969.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Terbi Aid 250mg Tablet
	Composition	"Each tablet contains: Terbinafine(as hydrochloride)…250mg"
	Diary No. Date of R& I & fee	Dy.No.21655 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg of M/sNeomedix Pharmaceuticals
	GMP status	
	Remarks of Evaluator	Fee challan is for Terbi Aid 250mg Capsule instead of Terbi Aid 250mg Tablet. Clarification regarding applied formulation is coated or uncoated.
	Decision: Deferred for the following: • **Clarification regarding applied formulation is coated or uncoated.** • **Submit Fee challan for relevant formulation.**	
2970.	**Name and address of manufacturer / Applicant**	**"M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur"**
	Brand Name +Dosage Form + Strength	Isonic 20mg Capsule

	Composition	"Each hard gelatin capsule contains: Isotretinoin…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21656 dated 20-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Retinoid for topical use in acne
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	5's, 10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Atractin20mg Capsule of Genome
	GMP status	GMP inspection conducted on 16-03-2017 concluded that firm is operating at good level of GMP compliance.
	Remarks of Evaluator	Evidence of section approval & equipment used in manufacturing of applied formulation is required. Applied formulation is hard shell capsule stability studies may be needed.
	Decision: Deferred for the following: • **Evidence of section approval & equipment used in manufacturing of applied formulation is required.** • **Applied formulation is hard shell capsule so submit stability studies as per guidelines approved in 293rd meeting of Registration Board.**	
2971.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan By Medisure Lab Pvt Ltd"**
	Brand Name +Dosage Form + Strength	Iroaid 100mg/5ml Injection
	Composition	"Each 5ml contains: Iron sucrose eq. to elemental Iron….100mg"
	Diary No. Date of R& I & fee	Dy.No. 20883 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Acron S 100mg/5ml Injection of Asian Continental
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for the following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.** • **Mention type of primary packaging material of applied formulation.**	
2972.	**Name and address of manufacturer / Applicant**	**"M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan By Medisure Lab Pvt Ltd"**

	Brand Name +Dosage Form + Strength	Seafix 100mg/5ml Suspension
	Composition	"Each 5ml contains: Cefixime (as trihydrate)….100mg"
	Diary No. Date of R& I & fee	Dy.No 20882 dated 11-06-2018 Rs.50,000/- Dated 11-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status (with strength and dosage form)	Seaxim Dry Suspension of Semos Pharmaceuticals
	GMP status	GMP Inspection conducted on 10th May, 2017 stated that firm is operating at an acceptable level of GMP Compliance with the potential to improve further.
	Remarks of Evaluator	Mention type of primary packaging material.
	Decision: Deferred for type of primary packaging material of applied formulation.	
2973.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine(as hydrobromide)…20mg"
	Diary No. Date of R& I & fee	Dy.No. 21069 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2974.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 97/103 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan…103mg"
	Diary No. Date of R& I & fee	Dy.No.21065 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Neprilysin Inhibitors ,angiotensin receptor blocker,
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications

	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2975.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Lacomide 10mg/ml Syrup
	Composition	"Each ml Contains: Lacosamide…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21067 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Anti-epileptic drug
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	60ml,90ml,120ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in Belgium, Germany, Ireland, Malta & UK
	Me-too status (with strength and dosage form)	Lalap syrup 10mg/ml by Genix Pharma (Reg#089376)
	GMP status	Panel Inspection for renewal of DML conducted on 18th & 31st July recommended grant of renewal of DML.
	Remarks Of Evaluator	Applied formulation is new molecule for which submission of stability studies & fee Rupee 50,000 is required.
	Decision: Approved.	
2976.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 49/51 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg"
	Diary No. Date of R& I & fee	Dy.No.21066 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	-----
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.

	Remarks Of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2977.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Revocard 24/26 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril…24mg Valsartan…26mg"
	Diary No. Date of R& I & fee	Dy.No. 21064 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	angiotensin receptor blocker, angiotensin receptor blockers
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30,s : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	------
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is subsequent drug generic version for which submission of stability studies are required before further processing of case.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2978.	**Name and address of manufacturer / Applicant**	**"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Vortiox 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine (as hydrobromide)…10mg"
	Diary No. Date of R& I & fee	Dy.No.21070 dated 12-06-2018 Rs.20,000/- Dated 08-06-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	As per Innovator's Specifications
	Pack size & Demanded Price	10's, 20's,30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel Inspection for renewal of DML conducted on 18th& 31st July recommended grant of renewal of DML.
	Remarks of Evaluator	Applied formulation is a new molecule for which fee 50, 000 & stability studies are required before further processing.

	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board.	
2979.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Palidol 3mg Tablet
	Composition	"Each Extended Release Tablet Contains: Paliperidone…3mg"
	Diary No. Date of R& I & fee	Dy.No.21234 dated 13-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	As per innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved USFDA
	Me-too status (with strength and dosage form)	Avega 3mg Tablets of M/s Biogen Pharma (Pvt) Ltd, Islamabad.
	GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.
	Remarks of Evaluator	Submit evidence of purchase of all equipment involved in manufacturing of applied formulation including laser drill.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2980.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 12.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No. 30866 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier

		layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	
2981.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 25mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 30867 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	
2982.	Name and address of manufacturer / Applicant	M/s The SchazooZaka Pvt Ltd. Lahore Kalalwala, Zakaur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Parotin CR 37.5mg Controlled Release Tablet
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 30868 dated 13-09-2018 Rs.20,000/- Dated 13-09-2018

	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Dated: 26-06-2018 & 27-06-2018 GMP Certificate issued on 24-07-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti Tb) 4- Sachet (Gen, Anti Tb).
	Remarks of the Evaluator	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.
	Decision: Deferred for the following: • **Submit label claim of applied formulation in line with reference product which is approved as enteric coated controlled release tablet.** • **Submit manufacturing method of applied formulation in line with the innovator product which consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.**	

Case no. 02 Registration applications of categories to be considered on priority

c. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

2983.	**Deleted as the case was already approved.**	
2984.	**Deleted as the case was already approved.**	
2985.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oranib 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sorafenib as tosylate…200mg"
	Diary No. Date of R& I & fee	Dy.No 4887 dated 02-02-2019 Rs.20,000/-
	Pharmacological Group	Kinase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications
	Pack size & Demanded Price	10's, 30's, 60's, 120's, :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	NEXAVAR 200MG TABLETS of BAYER PAKISTAN
	GMP status	Dated: 04-07-2018 **Conclusion:**

		Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing facility.	
2986.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Semotrozole 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Anastrozole…….1mg"
	Diary No. Date of R& I & fee	Dy.No 4885 dated 04-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturers' Specifications
	Pack size & Demanded Price	10's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	ARMOTRAZ TABLETS 1mg Of AJ MIRZA PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2987.	Name and address of manufacturer / Applicant	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha
	Brand Name +Dosage Form + Strength	Lozet 2.5mg Tablet
	Composition	Each Film Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No 5180 dated 06-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	30's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product with USP specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2988.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tomifen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Tamoxifen Citrate…10mg
	Diary No. Date of R& I & fee	Dy.No 5155 dated 06-02-2019 Rs.20,000/-

	Pharmacological Group	Anti-oestrogen
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA(EQ 10MG BASE **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	
	GMP status	Dated: 10-07-2019 **Concluding Remarks:** Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator.	Reference product is approved as Tamoxifen as citrate 10mg uncoated tablet.
	Decision: Deferred for the following : **Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. Tamoxifen as citrate 10mg uncoated tablet. Along with submission of requisite fee, master formulation & manufacturing method.**	
2989.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neoplaxol 100mg/5ml Injection
	Composition	Each 5ml ampoule contains: Etoposide as phospate…100mg
	Diary No. Date of R& I & fee	Dy.No 5592 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (5ml):As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	SEDOL 100MG/5ML INJECTION of Helix
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2990.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Irotec 300mg Injection
	Composition	Each ml contains: Irinotecan Hcl Trihydrate…20mg

	Diary No. Date of R& I & fee	Dy.No 5587 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Other antineoplastic agents
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's (15ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	IRINOTECAN EBEWE 100MG/5ML of Novartis
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2991.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 80mg/2ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous 80mg polysorbate…80 qs 2ml
	Diary No. Date of R& I & fee	Dy.No 5589 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA Aproved in USFDA (40MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**)
	Me-too status	TAXOTERE INFUSIONEACH VIAL CONTAINS DOCETAXEL TRIHYDRAT (AS ANHYDROUS) 80MG, POLYSORBATE 80PB Q.S TO 2ML of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision: Deferred for the following: • **Justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Status of Diluent whether it is combo pack or otherwise.**	
2992.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rubidox P 50mg/25ml Injection

	Composition	Each ml contains: Doxorubicin hydrochloride…2mg (as lposomalpegylated)
	Diary No. Date of R& I & fee	Dy.No 5607 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Anthracyclines and related substances
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(25ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.**	
2993.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxetal 20mg/0.5ml Injection
	Composition	Each injection vial contains: Docetaxel anhydrous… 20mg polysorbate…80 qs 0.5ml
	Diary No. Date of R& I & fee	Dy.No 5595 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's(0.5ml) vial: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	TAXOTERE I.V. INFUSIONE of R.P.R. KARACHI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Terminal sterilization not mentioned Packaging material not mentioned submit separate application for diluent
	Decision:Deferred for the following: • **Submit justification on scientific grounds for not performing terminal sterilization of applied formulation.** • **Mention type of primary packaging material of applied formulation whether it is type I, II, or III glass container.** • **Submit separate application for diluent.**	
2994.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cisplat 50mg/100ml Injection
	Composition	Each ml contains: Cisplatin…0.5mg

	Diary No. Date of R& I & fee	Dy.No 5608 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Platinum compounds
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's (100ml vial): As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	QUIRAL QUIMICA of NEOMEDIX RAWALPINDI
	GMP status	GMP inspection conducted on 19.09.2018 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2995.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Menocar Tablets 2.5mg
	Composition	Each Film Coated Tablet Contains: Letrozole …2.5mg
	Diary No. Date of R& I & fee	Dy.No 5369 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	Rs.291.66/tablet, Rs. 8750/ 30tablets: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 18-10-2019 Certificate of GMP issued on 18-10-2019.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
2996.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, KotLakhpat, Lahore
	Brand Name +Dosage Form + Strength	Virin 4 Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy.No 5334 dated 07-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's,40's,50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Revirin-C tablet of High-Q
	GMP status	Dated: 27-08-2018, 05-10-2018, 06-11-2018 **Recommendations:** The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.

	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
2997.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 200mg Tablets
	Composition	Each Tablet Contains: Acyclovir…200mg
	Diary No. Date of R& I & fee	Dy.No 5802 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Anti viral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Clovir 200 mg Tablets of Glitz Pharam, Kahuta Road P.No.265, Industrial Triangle, Islamabad
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2998.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 800mg Tablet
	Composition	Each Tablet Contains: Acyclovir…800mg
	Diary No. Date of R& I & fee	Dy.No 5804 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's,15's,20's,25's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Virocyc Tablets of Global Pharmaceuticals
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and

		facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
2999.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, SundarRaiwindRaod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Danvir 400mg Tablet
	Composition	Each Tablet Contains: Acyclovir…400mg
	Diary No. Date of R& I & fee	Dy.No 5803 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Cyclor Tablets of Candid Pharmaceuticals,
	GMP status	Dated: 08-03-2019 **Recommendations** The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going thrpugh the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	
	Decision: Approved	
3000.	Name and address of manufacturer / Applicant	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan-75700
	Brand Name +Dosage Form + Strength	Ovara 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 5902 dated 11-02-2019 Rs.20,000/-
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	Dated: 11-05-2018 **Conclusion:**

		Based on the areas visited, people met and commitment of the firm for continuous improvement. It is concluded that the firm is operating at a **Good level of GMP compliance** at the time of inspection.
	Remarks of the Evaluator.	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
3001.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 250mg
	Composition	Each dispersible tablet contains: Deferasirox…250mg
	Diary No. Date of R& I & fee	Dy.No 6958 dated 19-02-2019 Rs.20,000/-
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Oderox 250mg tablet of AJ mirza
	GMP status	Dated: 20-09-2017 Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's specification.	
3002.	Name and address of manufacturer / Applicant	M/s Fynk Pharmaceuticals. 19km G.T. Road KalashahKaku, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Afsirox Dispersible Tablet 500mg
	Composition	Each dispersible tablet contains: Deferasirox…500mg
	Diary No. Date of R& I & fee	Dy.No 6957 dated 19-02-2019 Rs.20,000/
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	ODEROX -500 DISPERSIBLE TABLET of M/S. AJ MIRZA PHARMA (PVT) LTD.,
	GMP status	Dated: 20-09-2017 Conclusion: "Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."
	Remarks of the Evaluator.	

	Decision: Approved as per innovator's specification.	
3003.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Oxy Z 500mg Capsule
	Composition	Each Capsule Contains: Hydroxyurea…500mg
	Diary No. Date of R& I & fee	Dy.No 8123 dated 25-02-2019 Rs.20,000/-
	Pharmacological Group	Antimetabolite
	Type of Form	Form-5
	Finished product Specification	Mfg Specifications
	Pack size & Demanded Price	1's, 10's, 1000's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	HYDAB 500MG CAPSULE of ATCO PHARMA
	GMP status	Dated: 04-07-2018 **Conclusion:** Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of required manufacturing facility.	

Case no. 03 Registration applications of import cases

c. New Cases (Human)

3004.	Name and address of Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. House # 166-A, Street # 9, Chaklala Scheme III, Rawalpindi
	Detail of Drug Sale License	License to sell drugs as distributor No. 0011000 0002403 valid upto 28-Aug-2020.
	Name and address of manufacturer	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name and address of marketing authorization holder	M/s MefarIlacSanayii A.S. RamazanogluMah. Ensar Cad. No:20, 34906 Kurtkoy-Pendik, Istanbul, Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No. 31977 dated 25-09-2018 Rs.100,000/- Dated 25-09-2018
	Fee including differential fee	Rs.50,000/- Dated 21-05-2018
	Brand Name +Dosage Form + Strength	Calderol 1mcg/ml Solution for IV Injection
	Composition	"Each ml Contains: Calcitriol……..1mcg"
	Finished Product Specification	Manufacturer's specifications
	Pharmacological Group	Vitamin D analogue
	Shelf life	36 months as per the stability study data of the product conducted as per conditions of zone IV-B
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Approved in USFDA
	Me-too status	
	Detail of certificates attached	CoPP (No. 2018/2203) issued by Turkish medicines and medical devices agency dated 04-06-2018 for calderol 1mcg/ml solution for IV injection which confirms the free sale

		status of the product in country of origin as well as GMP status of the manufacturer. The certificate was valid till 04-06-2020.
	Remarks of the Evaluator	
	Decision: Approved as per the policy for inspection of manufacturer abroad. Firm will provide valid, legalized CoPP before issuance of Registration letter.	

Case No. 04 Registration applications of drugs for which stability study data is submitted

c. Verification of stability study data

3005.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Sofosbuvir Tablet 400mg
	Composition	Each film coated tablet contains: Sofosbuvir…. 400mg
	Diary No. Date of R& I & fee	R&I date: 27-08-2018 Fee 20,000/- (20-08-2018) Duplicate dossier
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	28's(HDPE bottle): As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	N/A

STABILITY STUDY DATA

Drug	Sofosbuvir Tablet 400mg		
Name of Manufacturer	M/s Zafa Pharmaceutical Laboratories, L-1/B, Block 22, Federal "B" Industrial Area, Karachi.		
Manufacturer of API	Optimus Drugs PVT Limited, Factory, Sy No. 239 & 240 Dothigudam(V) Pochampally(M), Nalgonda Dist., Telangana, India		
API Lot No.	**Batch No.**OP-GLD/10/15/037		
Description of Pack (Container closure system)	28's; HDPE Bottle		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real Time: 0,4,8,12,24 MonthsAccelerated: 0,4,8,12,24 Months		
Batch No.	Tr-01	Tr-02	Tr-03
Batch Size	212 tablets	212 tablets	212 tablets
Manufacturing Date	August, 2017	August, 2017	August, 2017
Date of Initiation	22th August, 2017	22th August, 2017	22th August, 2017
No. of Batches	03		
Date of Submission	28-06-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
33.	COA of API	Firm has submitted copy of COA stating following information on it: **Product:**Sofosbuvir **Batch No.**OP-GLD/10/15/037 **Manufacturer:**Optimus Drugs PVT Limited,

34.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted GMP certificate having following information on it: **Certificate No.**L.Dis.No.20121/A3/2018 **Issued to:**Optimus Drugs PVT Limited, **Issued on:** 21-05-2018 **Validity:** One Year From The Date Of Issue
35.	Protocols followed for conduction of stability study and details of tests.	Yes
36.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
37.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice stating following information on it: **Invoice No.** 412/EXP **Batch No of API.** OP-GLD/10/15/037 **Attested by Assistant Director (I & E) DRAP Karachi On** : 03-02-2016
38.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
39.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
40.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

SOFOSBUVIR TABLET 400MG, M/S ZAFA PHARMACEUTICALS LABORATORIES.

Following panel of inspectors visited M/s Zafa Pharmaceuticals Laboratories for verification of authenticity of submitted stability study data for registration of Sofosbuvir 400mg Tablet.

1. Syed Adnan Rizvi Director, DTL, Karachi.
2. Dr. Najam-us-Saquib Additional Director DRAP, Karachi.
3. Kirshan, Assistant Director, DRAP, Karachi.

Q.No.	Question	Observation by panel
73.	Do you have documents confirming the import of API including approval from DRAP?	The firm has imported Sofosbuvir from Optimus Drug Pvt. Ltd. Hyderabad INDIA, Supplier IRIS Karachi. Invoice No.412/EXP dated 15-11-2015. Batch # OP-GLD/10/15/037. The total quantityofAPI purchased was1.00 kg.The approval from DRAP is available. (Annex-A)
74.	What was the rationale behind selecting the particular manufacturer of API?	Rationale behind selecting the particular manufacturer of API, as it is GMP compliant and vendor evaluation has been done. (Annex-B).
75.	Do you have documents confirming the import of reference standard and impurity standards?	The reference standard & impurity standard were imported through Optimus Drug Pvt. Ltd. Hyderabad INDIA. In House Reference standard, Batch # OP-SFS/RS1402, quantity100mg.Impurity standard, Batch # OP-GLD/St-I/Rp-Isomer/A0453/055, with quantity 10.0mg. (Annex-C)
76.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has COAs for API, reference standards and impurity.

77.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP Certificate of API manufacturer issued by Drug Control Administration Govt. of TelanganaINDIA.L.DisNo. 2021/A3/2018 Dated 21-05-2018.
78.	Do you use API manufacturer method of testing for testing API?	The Firm has used manufacturer's method of testing for the testing of API.
79.	Do you have stability studies reports on API?	The firm has manufacturers Stability studies report of API.
80.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing as per SIM method and degradation products has been quantified by the API manufacturer.
81.	Do you have method for quantifying the impurities in the API.	The firm has used HPLC method for chromatographic impurities that was used for assay purpose.
82.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some quantities of API (As reference), reference standard.
83.	Have you used pharmaceutical grade excipients?	The firm has used Pharmaceutical grade excipients
84.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
85.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records of the excipient used.
86.	Do you have written and authorized protocols for the development of applied product?	The firm has written protocol for the development of Sofosbuvir Tablets 400 mg.(Annex-D)
87.	Have you performed Drug-excipient compatibility studies?	The firm has not performed drug excipient compatibility studies because the composition of their tablets/product is similar to that of the innovator's product (Sovaldi Tablets)
88.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies and their product show comparable dissolution profile and same were reviewed at time of inspection.
89.	Do you have product development (R&D) section.	The firm has separate new product development (R&D) section.
90.	Do you have necessary equipments available in product development section for development of applied product?	The firm has used Quality Control Lab instruments for the development of Sofosbuvir Tablets 400 mg. The firm has all necessary equipment in QC and Product development section.
91.	Are the equipment in product development section qualified?	All the equipment used in the development of product is qualified.
92.	Do you have proper maintenance / calibration / requalification program for the equipment used in PD section?	The firm has proper maintenance and calibration for the equipment used in quality Control for the development of the product.
93.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff for the development of the product with proper knowledge and training in product development. (Annex-E)
94.	Have you manufactured three stability batches for the stability studies of applied products required?	The firm has manufactured three stability batches, of Sofosbuvir Tablets 400 mg, TR01, TR02, TR03.
95.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability of batches are the number of tablets as per requirement of testing.
96.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. All the log books are properly maintained and reviewed at the time of inspection.
97.	Do you have protocols for stability testing of stability batches?	The firm has protocols for testing of the stability batches.

98.	Do you have developed and validated the method for testing of stability batches?	Yes, the firm has used manufacturer's method of testing, the method is validated.
99.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
100.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, the firm has proper documents confirming the qualification of equipment and instruments being used in the test and analysis of API and the finished product.
101.	Do your method of analysis stability indicating?	Yes the method of analysis is stability indicating.
102.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR compliant.
103.	Can you show Audit Trail reports on Stability study testing?	The firm showed the Audit trail report on API and finished product testing.
104.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
105.	Do you have commitment batches kept on stability testing?	The firm has three commitment batches kept on stability testing for real time stability studies.
106.	Do you have valid calibration status for the equipment used in Production and analysis?	Yes, the firm has valid calibration status for the equipment used in the production and analysis of Sofosbuvir Tablets 400 mg.
107.	Do proper and continuous monitoring and control are available for stability chambers.	Continuous power supply and monitoring and control are available for the stability chambers.
108.	Do related manufacturing area, equipment, personal and utilities be used as GMP compliance	The relevant manufacturing facilities are GMP complaint.

Conclusion:

M/s Zafa Pharmaceutical Laboratories was inspected as per directions contained in DRAP letter No. 13-11/2017-PEC (Pt) dated 30th July, 2019. During inspection, the panel inspected/reviewed the relevant record, data and premises in detail with specific focus on the observations/points made in above referred letter. Following are the current observations:

9. **Criterion/reference for selection of Q Value 70%:** - The said molecules was not included in any official monograph, therefore, the firm previously performed the dissolution test as per general requirement for dissolution testing and there was no any specific criteria for the selection of Q value 70%. Now, the firm have performed dissolution test for their product according to US-FDA recommended dissolution method and found it satisfactory at the time of inspection.

10. **Valid GMPCertificate** of API Manufacturer is hereby attached for reference.

11. On the basis of risk-based approach the genuineness/ authenticity of stability data submitted by the firm for registration of Sofosbuvir Tablets 400mg is verifiable to satisfactory level.

12. The related manufacturing area, equipment, personnel and utilities observed in line as per GMP requirements and well suited for manufacturing of the said product.

Recommendations:

Based on the people met, documents reviewed and observations made during inspection including corrective action taken by the firm, the panel unanimously recommends that the firm may kindly be granted necessary registration of Sofosbuvir Tablets 400mg.

Decision(M-294): Registration Board decided to defer the case for following submissions:

- Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.
- Valid GMP certificate of the API manufacturer.

Now the applicant has submitted following:

Applicant has referred to their Comparative dissolution profile of applied formulation with reference product and submitted results declaring drug release profile of applied formulation is greater than 90 % within 15 minutes.

Decision: Registration Board keeping in view its decision taken in 293rd meeting decided to defer the case for following submissions:

- **Submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.**
- **Valid GMP certificate of the API manufacturer.**

3006.	Name and address of manufacturer / Applicant	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.
	Brand Name +Dosage Form + Strength	Helisopt Ophthalmic Suspension
	Composition	Each ml ophthalmic suspension contains: Brinzolamide...……..…10mg Timolol (as maleate)…….5mg
	Diary No. Date of R& I & fee	Duplicate dossier
	Pharmacological Group	Carbonic Anhydrase Inhibitor, Beta-adrenergic blocking agent.
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP compliant dated 10-08-2017.

STABILITY STUDY DATA

Drug	Helisopt Ophthalmic Suspension		
Name of Manufacturer	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.		
Manufacturer of API	**Timolol (as maleate):** M/s. Gangwal Chemicals Pvt. Ltd., Plot No. N-5 Mide, TarapurBoisar, District: Thane 01 506, India **Brinzolamide:** M/s. Century Pharmaceuticals 103 to 106, GIDC, Halol, 389 350, Dist: PANCHMAHAL, Gujrat State, India.		
API Lot No.	**Timolol (as maleate):** (Batch No. TMM-051656. Mfg date: May 2016, Quantity: 2kgs). **Brinzolamide:** (Batch No.07111004-BA. Mfg date: March 2016, Quantity: 80grams).		
Description of Pack (Container closure system)	(5ml) LDPE bottle		
Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) Accelerated: 0,3,6 Months		
Batch No.	TF 001	TF 002	TF 003
Batch Size	01 Litters	01 Litters	01 Litters
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	25-08-2017	25-08-2017	25-08-2017
No. of Batches	03		
Date of Submission	Dy No.12219, 03-04-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status

No.		
41.	COA of API	Yes
42.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Timolol (as maleate):** Copy of GMP certificate bearing a number NEW-WHO-GMP/CERT/KD/50623/2016/11/17467 issued to M/s. Gangwal Chemicals by Food & Drug Administration Maharashtra, India. Valid until 02-12-2018. **Brinzolamide:** Copy of GMP certificate bearing a number 1707219 issued to M/s. Century Pharmaceuticals by Food & Drug Control Administration, Gujarat state India. Valid until 06-07-2019.
43.	Protocols followed for conduction of stability study and details of tests.	Yes
44.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
45.	Documents confirming import of API etc.	**Timolol (as maleate):** Copy of Form 5 (license to import Drugs) issued by ADC, DRAP, Karachi dated 04-07-2016 has been submitted. Copy of commercial invoice has been submitted. **Brinzolamide:** Copy of Form 6 (license to import Drugs for clinical trial examination) issued by ADC, DRAP, Karachi dated 21-09-2016 has been submitted. Copy of ADC attested commercial invoice has been submitted.
46.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
47.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
48.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR & REPLIES OF APPLICANT

- The firm has claimed Manufacturer's Specifications and the product is not present in available USP & BP.
- Submit raw data sheets of analytical method of applied formulation.
- Commitment to follow Drug Specification Rules, 1978.
- Commitment to continue real time stability studies till the proposed/assigned shelf life.
- Latest GMP inspection report conducted within the period of last one year.
- Chromatographic conditions in the finished product testing method submitted in dossier is different to that submitted with stability studies. Clarify/Justify.

Applicant has submitted that "We have applied for product dossier file on 20-04-2012, at that time, we did not have HPLC complies Software 21CFR but now we have all HPLCs complies with software 21CFR and we are working on HPLC with software 21CFR for new product's stability studies. Therefore you found the difference in chromatographic conditions & current chromatographic conditions upon which stability studies are performed are following: wavelength 280nm & flow rate 1ml/minute".

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Helisopt Ophthalmic Suspension (Brinzolamide/Timolol) by M/s. Helix Pharma , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 10th December, 2018.
Investigation Date and Time: 18th December, 2018 (Forenoon).
Investigation Site: Factory premises of M/s. Helix Pharma, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Helix Pharma, Karachi for registration of Helisopt Ophthalmic Suspension each ml of which contain Brinzolamide 10mg and Timolol (as maleate) 5mg and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

7. Dr. Abdul Waheed, Assistant Director, CDL, DRAP, Karachi
8. Mr. Adnan Rizvi, Director DTL Sindh, Karachi (Member Registration Board)
9. Dr.Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Helisopt Ophthalmic Suspension

S.No.	Question	Observation by panel
1	Do you have documents confirming the import of API ?	The firm has imported 80g Brinzolamide from M/s Century Pharmaceuticals Limited, India vide invoice no. EXP16087 dated 2-09-2016 and 4.0 kg from M/s Gangwal Chemical Pvt. Ltd. India vide invoice No. EXP-T/030/16-17 dated 05.01.2017 and obtained approval from DRAP Karachi
2	What was the rationale behind selecting the particular manufacturers of APIs?	There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF etc. The firms were evaluated on above mentioned criteria and selected
3	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of both APIs USP reference standard and impurity standards.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs, working standards and their impurities.
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of Brinzolamide and timolol manufacturers issued by Food and Drug Control Administration, Gujrat State, India and Food and Drug Administration, Mahrashtra, India respectively.
6	Do you use API manufacturer method of testing?	The firm has used USP method of testing for both APIs.
7	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months on both APIs and five years and four years real time stability studies reports on the Brinzolamide and Timolol respectively.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9	Do you have method for quantifying the impurities in the API?	The firm has USP method for quantifying the impurities in the API.

<table>
<tr><td>10</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has remaining quantities of API and reference standard of both APIs.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has documents confirming the procurement of all excipients used.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of API ophthalmic suspension?</td><td>The firm has written and authorized protocols for the product development.</td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>N/A</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with equipment for manufacturing of ophthalmic suspension dosage form. The analytical part is performed on equipment of routine quality control tests.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of API ophthalimic suspension?</td><td>The firm has necessary equipment for product development of API ophthalmic suspensions. The product in question has been developed while using some equipment of commercial manufacturing also. Furthermore, the analytical part has been performed via the routine quality control equipment. Firm has already placed orders for procurement of other equipment for this section.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff which include One Chemist and One Pharmacist in product development section with relevant work experience.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of API ophthalmic suspension as required?</td><td>The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Helisopt ophthalmic suspension packed in LDPE bottles of 5ml each.
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg Date</td></tr>
<tr><td>TF 001</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 002</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 003</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
</table></td></tr>
<tr><td>23</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of bottles per testing and the number of bottles required for whole stability testing.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for stability testing of stability batches in which the stability conditions are:
Real Time: 30°C and 65% RH
Accelerated: 40°C and 75% RH,</td></tr>
</table>

		however, the firm has used LDPE container for the product in question for which ICH guidelines and WHO recommends 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies.
26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches. The method is supported by impurities standards spiking studies, forced degradation, hence capable of quantifying the degradation products in their ophthalmic suspension kept on stability testing.
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
28	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
30	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 12 months studies have been completed with satisfactory results.
34	Do you have valid calibration status for the equipment used in API ophthalmic suspensions production in analysis?	The firm has valid calibration status for the equipment used in helisopt ophthalmic suspension production and analysis.
35	Do proper and continuous monitoring and control are available for stability Chamber?	Continuous power supply and monitoring are available for stability chambers.
36	Do related manufacturing area, equipment, personnel and utilities be Rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.

Discussion:

11. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Helisopt Ophthalmic Suspension is verifiable to satisfactory level.
12. Furthermore, the firm has conducted the stability studies as per their protocol which is 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies, whereas, the recommended stability conditions for products packed in semi-permeable containers are 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. However, 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies may be used for semi-permeable containers provided the calculated water loss multiplied with the corresponding factor may not exceed 5% of initial, which is considered as significant change.
13. In this case the firm has not calculated water loss at any stage, so no comparison can be made between the reference and alternative relative humidity as mentioned in ICH Q1A (R2) (2.2.7.3. Drug products packaged in semi-permeable containers).
14. On risk-based approach the data evaluated during inspection does not show any deviation in the critical tests throughout the study period which may be altered if the water has lost more than the prescribed limits.

15. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Helisopt Ophthalmic Suspension.

Recommendations:

The firm may be granted necessary registration of Helisopt Ophthalmic Suspension in their name with the direction to conduct stability studies on their commitment batches as per ICH guidelines i.e. 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies and submit the data to the Drug Registration Board.

Previous Decision:

Registration Board in its 287th meeting decided as follow:

Registration Board deferred the case for submission of stability data at next time point of long term stability studies along with assessment of water loss rate for applied container closure system as per ICH Q1A (R2) guidelines for "Stability Testing of New drug substances and products."

Evaluation by PEC:

Applicant has submitted results of Water loss test in the form of graphs conducted on following newly manufactured batches of applied formulation.

Sr. No.	Batch No.	Batch Size.
1.	TF004	90 bottles
2.	TF005	90 bottles
3.	TF006	90 bottles

Decision:

Deferred for submission of formula by which results of moisture loss from the semipermeable container are calculated as well as submit details of readings used to plot the graph, as only graphs are submitted.

Evaluation by PEC:

Now the applicant has submitted following:

5. Formula by which results of moisture loss from the semipermeable container are calculated.
6. Readings used to plot the graph with the conclusion that moisture loss from the semipermeable container is within permissible limits.

Decision: Registration Board decided to approve registration of "Helisopt Ophthalmic Suspension" by M/s Helix Pharmaceuticals. Manufacturer shall place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Evaluator-PEC--X

Case No.1: Disclosure of Excipients on Labelling and leaflets for information of patients and prescribers.

It is submitted that Registration Board in 291st meeting deliberated on the matter related to the disclosure of excipients on the labelling and packaging leaflet insert. Matter has been discussed with reference to various complaints received through Prime Minister's Pakistan Citizen's Portal by different patients and also direct requests for the availability of gluten-free medicines for the patients suffering from Celiac Disease. Decision of the Board is as under:

Registration Board considered and deliberated the matter at length and decided, keeping in view the miserable condition of patients suffering from Celiac Disease and increasing number of lactose-intolerant patients, as following: -

i. *Directive 2001/83/EC of the European Council dated 06 November 2001 shall be adopted as such whereby the recommendations and guidelines along with Annexure to those guidelines shall be mandatory for the Pharmaceutical Manufacturers with respect to disclosure of excipients (both quantitative and qualitative) employed in the preparation of drug products;*
ii. *It shall also be mandatory for the manufacturer to perform tests for the presence of Gluten their drug and to categorically identify on the Label with the statement that "Contains Gluten and Contraindicated for Patients with Gluten allergy" or "Free from Gluten and safe for patients of celiac disease";*
iii. *It shall also be mandatory for the manufacturer to perform tests for the presence of Lactose in their drug and to categorically identify on the Label with the statement*

that "Contains Lactose and Contraindicated for Patients with Lactose-intolerance" or "Free from Lactose and Safe for Patients suffering from Lactose-intolerance";

However subsequent review revealed various points, which needs to consider by Registration Board:

i. Point (i) of the above decision is to adopt the Directive of European Council along with disclosure of excipient both (qualitative and quantitative).Instead of disclosure of all the excipient *(both quantitative and qualitative)* It may be appropriate to focus on the disclosure of those excipients which have known action or effect (for e.g. Gluten containing excipients, lactose containing ingredients etc.) employed in the preparation of drug product in the light of article 54(d) and 64 of the reference directive 2001/83/EC of the European Council dated 06 November 2001. Both articles are narrated as under: Article 54(d) of the directive is as under:

A list of those excipients known to have a recognized action or effect and included in the guidelines published pursuant to Article 65. However, if the product is injectable, or a topical or eye preparation, all excipient must be stated;

In Article 65 of reference directive following is stated related to the list of excipients which must feature on labelling:

As necessary, the commission shall publish guidelines concerning in particular:

- *The list of excipients which must feature on the labelling of medicinal products and the way these excipients must be indicated.*

ii. If any of such excipients used in the manufacturing of formulation it will be mandatory for the manufacturer to categorically identify on the Label with the statement that "Contains gluten/Lactose and Contraindicated for Patients with celiac disease/ Lactose-intolerance" or "Free from gluten/Lactose and Safe for Patients suffering from celiac disease/Lactose-intolerance";

It is therefore, proposed that Registration Board may passed a direction to Pharmaceutical Manufacturer/Importer for the disclosure of those excipients (e.g. gluten containing excipients, lactose) which have a recognized action or effect on the labelling and leaflet for information of patient and prescriber so that the patients suffering from hypersensitivity to any of the ingredients of the drug may help themselves by avoiding allergic medication(s) and may opt safe option(s) for themselves.

Discussion: The Board has noted, according to the draft guidance document of FDA https://www.fda.gov/media/116958/download regarding "the Gluten in Drug Products and Associated Labelling" that most oral drug products are not expected to contain ingredients derived from wheat barley or rye, which are the major source of gluten. Moreover, the amount of gluten estimated to be potentially present in a unit dose of an oral drug product (less than 0.5 mg) is 237 significantly less than the range at which gluten is estimated to be present in a gluten-free diet (5 to 50 mg). This leads FDA to conclude that individuals who respond well to a gluten-free diet are at low risk of experiencing problems as a result of the possible presence of gluten in a drug product.

Decision: Keeping in view the above stated position/discussion, the Board, in order to avoid any possibilities of untoward reaction relating to the use of such excipient (containing gluten, lactose etc.) decided to advise the Manufacturers/Importers, to provide the information that "product contains gluten/lactose" on the labelling and packaging leaflet insert in accordance with rule 3 (h)(iii) of Drug Labelling and packaging Rules,1986.

Case No. 2: Registration of Vitamin-Mineral Formulations

Registration Board in its 295th meeting considered the Registration applications of vitamin and mineral formulations which are previously deferred in different meeting of Registration Board. While considering the Registration applications which are the Me-Too of CaC-1000 plus Effervescent Tablet of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited, the Board questioned formulation of CaC-1000 plus effervescent tablet containing 4mg of Vitamin D3 quantity above the

upper tolerable intake level (UL) which is in contradiction of following points of approved vitamin policy:

1. Those Vitamins and minerals above Recommended Daily Allowance (RDA) up to Tolerable upper intake level (UL) are considered as drug.
2. If any ingredient in the vitamin and mineral formulation is above UL, then it may allow only, if it is available in already defined Reference Regulatory Agencies, *for intended therapeutic purpose*, otherwise the Firm has to revise its formulation. Furthermore, single ingredient vitamins for certain disease conditions may be registered with therapeutic claim as per approved Reference Regulatory Agencies.

In the response of above matter M/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited, submitted the clarification letter in which it is stated that they are using 4mg concentrate powder of Vitamin D3 which is equivalent to 400 IU Vitamin D3 based on potency of material used. Firm also submitted the evidence of Certificate of Analysis of Dry Vitamin D3 100 SD/S which consists of free-flowing particle. They contain 100,000-110,000 IU (2.5-2.75 mg) vitamin D3 per gram finely dispersed in the matrix of modified food starch, sucrose and medium chain triglycerides. All-rac-alpha-Tocopherol and sodium Ascorbate are added as antioxidant. Silicon dioxide is added as a flow agent.

Further, firm provide the BP Monograph of Cholecalciferol Concentrate (Powder Form) and it is mentioned in the definition of monograph that the powder concentrates obtained by dispersing an oily solution of cholecalciferol in an appropriate matrix, which is usually based on a combination of gelatin and carbohydrates of suitable quality, authorized by the competent authority. The content of concentrate 90.0 percent to 110.0 percent of the cholecalciferol content stated on the label, which is not less than 100,000 IU/g. It may contain suitable stabilizer such as antioxidants.

Dry Vitamin D3 100 SD/S used in the manufacturing of CaC 1000 plus effervescent tablet contain 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm so 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Calculation of vitamin D3 on the basis of documents provided by the firm has been summarize as under:

Each gm of Dry Vitamin D3 100 SD/S contain …100,000-110,000 IU of vitamin D3
Each mg of Dry Vitamin D3 100 SD/S contain ….100 IU of vitamin D3
4 mg of Dry Vitamin D3 100 SD/S contain ….400IU of Vitamin D3

In the light of above/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited has requested for issuance of rectified registration letter of all the flavours of CaC-1000 plus Effervescent tablet. Initially CaC-1000 plus Effervescent Tablet has been registered in the name of M/s. Novartis Pharma, Jamshoro than, Registration board in its 270th meeting cancel the registration of product CaC-1000 plus effervescent tablet from the name of M/s. Novartis Pharma and approved grant of registration of product in the name of M/s. GlaxoSmithKline OTC (Pvt) Ltd., Jamshoro. Registration Board in its 278th meeting approved the change in flavour of CaC 1000 Plus Effervescent Tablet (Reg# 084750) from Pine Apple to Mango flavour. Moreover, more additional flavours Cola, Orange and Lemon are also approved for CaC
1000 Plus Effervescent Tablet with new registration numbers. Approval of change of Title/Name of Manufacturer (from M/s. GlaxoSmithKline OTC (Pvt) Ltd., Jamshoro to M/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited, Jamshoro) of below mentioned product has been granted dated 30th August, 2019. Detail of all the flavours along with their registration number is given as under:

Sr.no.	Reg.no.	Name of drug along with Composition and flavours	Date of Registration
1.	084750	CaC 1000 Plus Effervescent Tablet Each tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg	20-07-2017

		Cholecalciferol (Vitamin D3) ….4 mg Mango Flavour….20mg	
2.	089120	CaC 1000 Plus Effervescent Tablet Each tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg Cholecalciferol (Vitamin D3) ….4 mg Cola Flavour….20mg	21-05-2018
3.	089121	CaC 1000 Plus Effervescent Tablet Each tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg Cholecalciferol (Vitamin D3) ….4 mg Orange Flavour….20mg	21-05-2018
4.	089122	CaC 1000 Plus Effervescent Tablet Each tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg Cholecalciferol (Vitamin D3) ….4 mg Lemon Flavour….20mg	21-05-2018

Firm has requested for issuance of rectified registration letter of all the above flavours of CaC 1000 plus effervescent tablet with the following label claim:

Existing Label Claim	**Correct Label Claim**
Each Effervescent Tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg Cholecalciferol (Vitamin D3) ….4 mg	Each Effervescent Tablet contains: Calcium Carbonate….327 mg Ascorbic Acid (vitamin C) ….500 mg Calcium Lactate Gluconate……1000 mg Pyridoxine HCl (Vitamin B6) …10 mg Cholecalciferol (Vitamin D3) ….400 IU

Decision: Registration Board noted the technical information related to the concentrated powder of vitamin D3 used in the formulation of CaC-1000 plus Effervescent tablet of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited, Jamshoro and accordingly quantity of Vitamin D3 (within UL Limit) used in the formulation of CaC-1000 Plus Effervescent tablet is summarize as under:

Each gm of Dry Vitamin D3 100 SD/S contain …100,000-110,000 IU of vitamin D3
Each mg of Dry Vitamin D3 100 SD/S contain ….100 IU of vitamin D3
4 mg of Dry Vitamin D3 100 SD/S contain ….400IU of Vitamin D3

Further, in the light of above submitted information Registration Board approved the correction in label claim of all four flavours of CaC-1000 Plus Effervescent Tablet of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Limited, Jamshoro. The correct label claim is as under:

Each Effervescent Tablet contains:

Calcium Carbonate….327 mg
Ascorbic Acid (vitamin C) ….500 mg
Calcium Lactate Gluconate……1000 mg
Pyridoxine HCl (Vitamin B6) …10 mg
Cholecalciferol (Vitamin D3) ….400 IU

Case No. 3: <u>Cases which are deferred in the previous Meeting on the basis of above matter:</u>

2451.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, /Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Effervescent Tablet) Orange Flavour
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. 148 dated 18/03/2009 Rs. 8,000/- Differential fee (Photocopy) of Rs. 12,000/- submitted on 26/10/2017
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000 mg Calcium Carbonate….327 mg Vitamin C (Ascorbic Acid) ….500 mg Vitamin D3 ….4 mg Vitamin B6….10 mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R. O
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator.	Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000 IU (250mcg) while the used amount is 4000 mcg same amount is used in me-too.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follows, along with fee of Rs.5,000/- submitted on 10-09-2020. Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg

		Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg
	Decision: Approved with the following label claim: **Each Effervescent tablet contains:** **Calcium Lactate Gluconate….1000mg** **Calcium Carbonate….327mg** **Vitamin C (Ascorbic Acid) ….500mg** **Vitamin D3….400IU** **Vitamin B6….10mg**	
2452.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Mango Flavour) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3 ….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000 IU (250 mcg) while the used amount is 4000 mcg same amount is used in me-too also**.**
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU

		Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration application on Form 5-F.	
2453.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets **(Lemon Flavour)** (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3 ….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's, 20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration	

	application on Form 5-F.	
2454.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets **(Cola Flavour)** (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs. 20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3 ….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000 mcg same amount is used in me-too.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000 mg Calcium Carbonate….327 mg Vitamin C (Ascorbic Acid) ….500 mg Vitamin D3….400 IU Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration application on Form 5-F.	
2455.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Effervescent Tablet) (orange Flavour)

	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No.157 Dated 18/03/2009 Rs.8,000/- Differential fee (photocopy) of Rs.12,000/- has been submitted on 26/10/2017
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3 ….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000 IU (250 mcg) while the used amount is 4000 mcg same amount is used in me-too also**.**
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follows, along with fee of Rs.5,000/- submitted on 10-09-2020. Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg
	Decision: Approved with the following label claim: **Each Effervescent tablet contains:** **Calcium Lactate Gluconate….1000mg** **Calcium Carbonate….327mg** **Vitamin C (Ascorbic Acid) ….500mg** **Vitamin D3….400IU** **Vitamin B6….10mg**	
2456.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Mango Flavour) (Effervescent Tablet)

	Diary No. Date of R& I & fee	Dy. No. 6415 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	Application is received on Form-5 instead of Form 5F. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75 mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration application on Form 5-F.	
2457.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Lemon Flavour) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6413 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg

		Vitamin D3….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	Application is received on Form-5 instead of Form 5-F. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000 IU (250 mcg) while the used amount is 4000 mcg same amount is used in me-too.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration application on Form 5-F.	
2458.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Cola Flavour) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6414 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000 mg Calcium Carbonate….327 mg Vitamin C (Ascorbic Acid) ….500 mg Vitamin D3….4 mg Vitamin B6….10 mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's, 20's & 30's

	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000 IU (250 mcg) while the used amount is 4000 mcg same amount is used in me-too also.
	Previous Decision:	Registration in its 295th meeting decided as under: Deferred, as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL) further Registration Board is directed to the Registration Holder of Me-Too/generic to apply for the correction/amendment of composition in the concerned section with the prescribed fee.
	Response of the Firm	• Firm submitted the COA of Dry Vitamin D3 100 SD/S, containing 100,000-110,000 IU (2.5-2.75mg) of vitamin D3 per gm meaning that 400 IU of vitamin D3 is present in 4 mg of Dry Vitamin D3 100 SD/S and it is below the range of UL recommended by different international Agencies. Further firm applied for the correction of label claim as follow: Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg • Further firm applied for registration on Form-5 instead of Form-5F
	Decision: Registration Board deferred the case for submission of Registration application on Form 5-F.	

CaseNo.4: <u>Cases deferred in previous meetings of registration Board on the basis of Vitamin Policy</u>

2459.	Name and address of manufacturer / Applicant	M/s. Indus Pharma, 26-27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Trimet Syrup 120ml
	Composition	Each 15ml of reconstituted syrup Contain: Metopine……2.75 mg L-Lysin hydrochloride……250 mg DL-Carnitine hydrochloride….375mg Vitamin B1 (Thiamine HCL)….30mg Vitamin B6 (Pyridoxine HCL) ….30mg Vitamin B12 (Cyanocobalamin)…1000mcg
	Diary No. Date of R& I & fee	Dy. No.67; 07-07-2015; Rs.20,000/- (06-07-2015)
	Pharmacological Group	Appetite Stimulant
	Type of Form	Form 5

	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	Rs. 73.00 per 120ml pack
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Trimetabol syrup of M/s Sami (Reg.#012814) registered with the following composition: Metopineate Bromide….2.75mg, L-Lysine Hcl….250 mg, D-I-Carnitine Hcl 375mg, Vitamin B1 30mg, Vitamin B6 30mg, Vitamin B12 1000mcg
	GMP status	cGMP inspection conducted on 16-08-2017 concludes that firm has been operating at acceptable level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 274th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.
	Evaluation by PEC (AD PEC-XII)	In Me-too Metopineate Bromide is used in the formulation while in applied formulation Metopine is used by the firm, clarification is required. Further in approved UL table level of Metopine, L-Lysine and DL-carnitine has not included. Metopine is an appetite stimulant. L-Lysine is an amino acid and its estimate requirement in adult is 12mg/kg per day according to US IOM. DL-Carnitine is derived from amino acid.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting because the formulation contain Metopine which is an appetite stimulant.	
2460.	Name and address of manufacturer / Applicant	M/s. Indus Pharma, 26-27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Osyfen-D Tablet
	Composition	Each film coated tablet contains: Ossein mineral complex…830mg Calcium …177.6mg* Phosphorus…82.2mg Residual Mineral Salts….24.9mg Collagen….224mg Other proteins…66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni *Corresponding to approximately 440mg Hydroxyapatite Vitamin D….400 IU
	Diary No. Date of R& I & fee	Dy. No. 635, 27-04-2015 , Rs. 20,000/- (27-04-2015)
	Pharmacological Group	Mineral and electrolyte calcium preparation
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	Rs. 10.00/Tablet Rs. 300.0-0/-30's
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ossein by Caraway
	GMP status	16-08-2017, Acceptable

	Remarks of the Evaluator.	• Firm provided the following justification for overage. "It is to inform you that 5 % additional ossein mineral complex in the formulation is added to compensate for 5% water present in ossein mineral complex and to compensate for material loss during processing due to sticky nature of ossein mineral complex." • Atomic absorption Spectrophotometer verified from FID report.
	Previous Decision	Registration Board in its 274th meeting deferred for the submission of the following: • Justification for 5% overage of active ingredient in master formulation since the submitted justification is not acceptable on scientific grounds. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.
	Evaluation by PEC (AD PEC-XII)	Justification regarding the overage is still pending Latest GMP inspection report is required Firm provide the Me-Too product Ossein Tablet registered in the name of M/s. Caraway Pharmaceuticals (Reg.no.056017)
	Decision: Deferred for the submission of justification regarding the 5% overage of active ingredient in Master formulation.	
2461.	Name and address of the Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	RAPIGROW-C Sachet
	Composition	Each Sachet contains: Calcium Lactate Gluconate……. 1000 mg Vitamin C…… 500 mg Calcium carbonate……. 327 mg
	Diary No. Date of R & I & Fee	Dy. No. 978, Dated 10/11/2015, Rs 20,000/= Dated 10/11/2015,
	Pharmacological group	Calcium & vitamin supplement
	Type of Form	Form – 5
	Finished Product Specification	In House
	Pack Size & Demanded Price	Pack Size: 1's×10 Price: Rs. 160/- per pack of (1's×10).
	Approval status of product in Reference Regulatory Authorities	Cannot be confirmed
	Me – too status	Pluc Sachet by M/s Indus Pharma (Registration No. 039613)
	GMP status	Last inspection report dated 16th-28th Aug, 2018. Concludes, "The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance."
	Remarks of the Evaluator	• The firm has claimed In House manufacturing specification and the product is not present in USP/BP. • Availability in reference regulatory authorities cannot be confirmed.
	Previous Decision	Registration Board in its 274th meeting decided as under:

		Deferred for the evidence of approval status of the product in reference country
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of Me-Too product Pluc Sachet registered in the name of M/s. Indus Pharma Karachi (Reg.no. 039613) and CaC-1000 Sachet of M/s. GSK Consumer Healthcare (Reg.no.084643).
	Decision: Approved with Innovator's specifications.	
2462.	Name and address of manufacturer / Applicant	**M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**.
	Brand Name +Dosage Form + Strength	D-Vit syrup 120ml
	Composition	Each 10ml contains: Cholecalciferol……1000 IU
	Diary No. Date of R& I & fee	Dy. No.678; 25-04-2016; Rs.20,000/- (18-04-2016)
	Pharmacological Group	Vitamin D3
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10ml, 30ml, 60ml, 120ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Sunny D syrup of M/s Scottman Parma
	GMP status	Last inspection was conducted on 23-01-017 and the report concludes good GMP compliance.
	Remarks of the Evaluator.	The proposed drug couldn't be searched in any reference regulatory authority.
	Previous Decision	Registration Board in its 274th meeting decided as under: Deferred for confirmation of approval status of product in reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	• For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required. • Firm provide the evidence of Sapvit-D3 approved in EMA which has different composition as it contains 14,400 IU Cholecalciferol in 1 ml.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.	
2463.	**Name and address of manufacturer / Applicant**	**M/s Seatle (Pvt.) Ltd. Lahore**
	Brand Name +Dosage Form + Strength	Zeluv-D suspension
	Composition	Each 5 ml contains: Vitamin D_3 …. 400 IU Ossein mineral complex …. 250 mg Corresponding to: Calcium …… 53.5 mg Phosphorus……. 24.8 mg Residual minerals ….7.5 mg Collagen …… 67.5 mg Other proteins …… 20 mg Trace elements F, Mg, Fe, Zn, Cu, and Ni. *Corresponds to approx. 132.5 mg of Hydroxyapatite
	Diary No. Date of R& I & fee	Dy. No. 237, 25-06-2015, Rs. 20,000/- (24-06-2015)

	Pharmacological Group	Combination of multivitamin and trace elements
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60 ml & 120 ml As per brand leader's price
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Ossvit-D Suspension of M/s Kaizen Pharma Karachi (Reg.#073837)
	GMP status	Last inspection conducted on 09-01-2015 and report recommends the resumption of production.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation by any reference regulatory authority is required. • Evidence of approval of oral liquid section is required. • Evidence of availability of atomic absorption is required.
	Previous Decision	Registration Board in its 272nd meeting decided to deferred for submission of following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies Registration Board in its 249th meeting. • Evidence of approval of oral liquid section. • Evidence of availability of atomic absorption. • Latest GMP inspection report conducted within 1 year by DRAP.
	Evaluation by PEC (AD PEC-XII)	• Latest GMP inspection report (which should have been conducted within the period of last three year) is required. • Evidence of approval of oral liquid section is required. • Evidence of availability of atomic absorption is required. • Further firm provide the evidence of Me-Too product Ossvit-D Suspension registered in the name of M/s. M/s Kaizen Pharma Karachi (Reg.#073837)
	Decision: Deferred for the submission of following shortcomings: • **Latest GMP inspection report (which should have been conducted within the period of last three year) is required.** • **Evidence of approval of oral liquid section is required.** • **Evidence of availability of atomic absorption spectrophotometer is required.**	
2464.	**Name and address of manufacturer / Applicant**	**M/s Astellas Pharmaceutical (Pvt) Ltd. Industrial Estate, Hayatabad, Peshawar.**
	Brand Name +Dosage Form + Strength	Calcium Plus Syrup 210mg+350/IU/5ml
	Diary No. Date of R& I & fee	Diary No: 4381, 30/05/2017, Rs: 20,000/-
	Composition	Each 5ml contains: Calcium as phosphate tribasic…210 mg Cholecalciferol (Vitamin D-3) …350 IU (8.75mcg)
	Pharmacological Group	Calcium and Vitamin Supplement
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	120ml/As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Citra Cal Plus -D (USA) (Not Confirmed)

	Me-too status	Calcium Phosphate + D Syrup by M/s Baxter (Reg#073494)
	GMP status	GMP Inspection conducted on 13-11-2018 with the following conclusion: Overall the GMP Compliance of the firm is Good.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • The firm has submitted titration method for assay of calcium.
	Previous Decision	Registration Board in its 272nd meeting decided as under: Deferred for evidence of approval of applied formulation by reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	As per approved vitamin Policy "Those Vitamins and minerals above Recommended Daily Allowance (RDA) up to Tolerable upper intake level (UL) are considered as drug". Both of these ingredients are fall below RDA. (RDA Level of calcium for adult is 300-1300mg and vitamin D3 is 15mcg) Firm provide the evidence of Me-Too product Calcium Phosphate D Syrup registered in the name of M/s. Baxter Pharmaceuticals (Reg.no. 073494)
	Decision: Deferred, as both the ingredients used in the formulation are below RDA Level, accordingly not fall under the category of drug as per decision of 295th meeting of Registration Board.	
2465.	Name and address of manufacturer / Applicant	**M/s Bio Fine Pharmaceuticals, Multan**
	Brand Name +Dosage Form + Strength	Neuromax Plus Tablets
	Composition	Each film coated tablet contains: Mecobalamin……750 mcg Glucosamine…….750 mg Methyl Sulfonyl Methane….250 mg
	Diary No. Date of R& I & fee	Dy.No.83; 13-6-2011; Rs.12,000/- (11-9-2015); Rs.8,000/- (13-1-2011)
	Pharmacological Group	Vitamin and nutritional supplement
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	1x10's; Rs. 150/- per tablet
	Approval status of product in Reference Regulatory Authorities.	**Not Provided**
	Me-too status	**Not provided**
	GMP status	Last Inspection report 27-10-2016 Management has shown positive report towards compliance.
	Remarks of the Evaluator.	Availability in Reference Regulatory Authorities and me-too status cannot be confirmed.
	Previous Decision	Registration Board in its 272nd meeting decided as under: Deferred for evidence of approval status of applied formulation in reference regulatory authorities and me-too status.
	Evaluation by PEC (AD PEC-XII)	• **Firm did not provide the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**

		• **Latest GMP inspection report (which should have been conducted within the period of last three year) is required.**
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. OR** • **In case of new combination, evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.** • **Latest GMP inspection report (which should have been conducted within the period of last three year).**	
2466.	Name and address of manufacturer / Applicant	M/s Genix Pharma (Pvt.) Ltd, 44, 45-B, Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Vita-K1 Tablets 10 mg
	Diary No. Date of R& I & fee	Dy.No.113; 04-08-2014; Rs. 20,000/-
	Composition	Each tablet contains: - Phytonadione ……. 10 mg
	Pharmacological Group	Vitamin K
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's (alu/alu blister); As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not submitted
	Me-too status	Vitamin k tablet of Irza Pharma
	GMP status	Last GMP Inspection of M/s Genix Pharmaceuticals conducted on 26-01-2017 with conclusive remarks of acceptable level of cGMP compliance.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies is required.
	Previous Decision	Registration Board in its 271st decided as under: Deferred for evidence of approval status of formulation in applied strength in reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting.	
2467.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd Karachi.
	Brand Name +Dosage Form + Strength	E-Soft 600mg Soft Gelatin Capsule
	Diary No. Date of R& I & fee	Dy.1165, 28-11-2016, Rs. 20,000/-
	Composition	Each soft gelatin capsule contains: Vitamin E (alpha tocopherol) ….600 mg
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specifications
	Pack size & Demanded Price	As per PRC As per PRC
	Approval status of product in Reference Regulatory Authorities.	Evion by Merck India
	Me-too status	Zescap by M/s. Zafa

	GMP status	GMP inspection conducted on 21-02-2019, concluded with the following remarks: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	264th Registration Board held on 28-29th December, 2016. Deferred for evidence of approval in reference regulatory authorities & me-too status **Evaluation by PEC:** • Firm has stated following Me-too reference: Zescap 600mg Soft Gel Capsules by M/s Zafa Pharmaceutical Laboratories, Karachi. (Reg.# 030627) • Firm has provided following international reference: Evion Vitamin E capsules by M/s Merck but the approval status from reference agencies could not be confirmed. • Firm has claimed in house specifications but not provided the following documents in the light of decision of 267th RB meeting □ Product and formulation development data □ Manufacturing method development and process validation □ Analytical method development and validation against innovator's analytical method and innovator's product □ Comparative pharmaceutical equivalence against innovator's product including comparative dissolution profiling Stability data of the product for accelerated and real time period against innovator's product as a reference Formulation is found in USP.
	Previous Decision	Registration Board in its 270th meeting decided s under: Deferred for evidence of approval of applied formulation in reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	Evidence of approval of applied formulation in reference regulatory authorities is required as it is single ingredient formulation.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting.	
2468.	Name and address of manufacturer / Applicant	M/s. Crystolite Pharmaceuticals (Pvt) Ltd. Plot# 1 & 2, S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Osamin-D Suspension
	Diary No. Date of R& I & fee	Diary No: 3502, 17/04/2017, Rs: 20,000/-
	Composition	Each 5 ml contains: Vitamin D_3 … 400 IU Ossein Mineral Complex…400mg Corresponding to: Calcium…85.59 mg Phosphorus…39.61 mg Residual mineral salts…12 mg Collagen…107.95mg

		Other proteins…32 mg Trace Elements…Fl, Mg, Fe, Ni, Cu
	Pharmacological Group	Mineral+Vitamin
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	120ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not given
	Me-too status	Osnate-D Suspension by M/s AGP Pharmaceuticals
	GMP status	Inspection for renewal of DML with the following conclusion: Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommends the renewal of DML for Crystolite Islamabad for following sections. 1- Tablet section (gen) 2- Capsule section (gen) 3- Cream/ointment section (gen) 4- Topical lotion section (gen) 5- Cream/Ointment section (steroid) 6- Topical lotion section (steroid) 7- Oral Sachet (gen) 8- Soft gelatin capsule (gen) 9- Syrup section (gen)
	Remarks of the Evaluator.	• Commitments as per 251st DRB meeting not attached. • Approval status of product in Reference Regulatory Authorities not provided by firm. • Evidence of atomic absorption spectrophotometer not given.
	Previous Decision	Registration Board in its 270th meeting decided as under: Deferred for evidence of approval of applied formulation in the reference regulatory authorities and atomic absorption spectrophotometer.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-too product, Osnate –D Suspension registered in the name of M/s. AGP Ltd, Karachi. (Reg. No. 070854) • Firm provide the copy of inspection report conducted on 17-10-2017, in which the area FID stated the firm has Atomic Absorption Spectrophotometer.
	Decision: Approved with Innovator's specifications.	
2469.	Name and address of manufacturer / Applicant	Asian Continental, D-32, Site II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Calocin-D Tablet (830 mg +400 IU)
	Diary No. Date of R& I & fee	Dy. No.187, R&I Dated 17-11-14, Rs: 20,000/-
	Composition	Each film coated tablet contains: Ossein mineral complex…830 mg Hydroxyapatite compound 830 mg (eq. to calcium 177.6 mg, phosphorous 82.2 mg, residual mineral salts 24.9 mg, collagen 224 mg, other proteins 66.4 mg, trace elements F, Mg, Fe, Ni.Cu) Vitamin D……..400 IU
	Pharmacological Group	Calcium ,Vitamin D Supplement
	Type of Form	From 5
	Finished Product Specification	As per innovator Specifications.

	Pack size & Demanded Price	30's, Alu- Alu Blister, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ossopan MD by Xymogen ,USA
	Me-too status	Ossobon D by Platinum Pharmaceuticals (R. No. 044003)
	GMP status	GMP inspection report dated 03-06-2020 with the following conclusion: Based on the above observations their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	I. Presence of Atomic Absorption Spectrophotometer confirmed by FID inspection report. II. Referred product in reference regulatory authority could not be confirmed.
	Previous Decision	Registration board in its 270th meeting decided as under: Deferred for confirmation of approval status in reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too Product Ossobon D Tablet by M/s. Platinum Pharmaceuticals (Reg.no. 044003). • Firm provide the evidence of GMP inspection report dated 11th Nov, 2015, wherein the area FID stated that the firm has recently installed Atomic Absorption Spectrophotometer.
	Decision: Approved with Innovator's specifications.	
2470.	Name and address of manufacturer / Applicant	**Munawar Pharma, Lahore**
	Brand Name +Dosage Form + Strength	AM-D3 Oral liquid
	Diary No. Date of R& I & fee	115, 5-1-2011, Rs 8000, Rs 12000
	Composition	Each 10ml contains: Vitamin D_3 (cholecalciferol)….1000 IU
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	1's *120ml, Rs 165
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Sunny D Vitamin by Scotsman Pharma
	GMP status	Last Inspection report 28-7-2016 Firm has made improvement regarding the previous GMP Inspection and shown positive intentions to improve further.
	Remarks of the Evaluator.	International availability in RRA cannot be confirmed.
	Previous Decision	Registration Board in its 273rd meeting decided as under: Deferred for the evidence of approval of applied formulation in Reference Regulatory Authority.
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required. Latest GMP inspection report not old then three years is required.
	Decision: Deferred for the submission of following:	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.** • **Latest GMP inspection report not old then three years is required.**	
2471.	Name and address of manufacturer / Applicant	**Munawar –Pharma, Lahore**
	Brand Name +Dosage Form + Strength	Muna-Calc Suspension
	Diary No. Date of R& I & fee	116, 5-1-2011, Rs 8000, Rs. 12000
	Composition	Each 5ml suspension contains: Calcium Phosphate (Tribasic)…210 mg Vitamin D….350 IU (8.75mcg)
	Pharmacological Group	Calcium Supplement
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	120ml, Rs 60
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Calcium-P by PDH Pharma
	GMP status	Last Inspection report 28-7-2016 Firm has made improvement regarding the previous GMP Inspection and shown positive intentions to improve further.
	Remarks of the Evaluator.	➢ International availability in RRA is not confirmed. ➢ Firm has claimed Manufacturer's Specifications while product is present in USP.
	Previous Decision	Registration Board in its 273rd meeting decided as under: Deferred for the evidence of approval of applied formulation in Reference Regulatory Authority.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me- Too product which has different composition. Further both ingredients are fall below RDA Level. As per approved vitamin Policy "Those Vitamins and minerals above Recommended Daily Allowance (RDA) up to Tolerable upper intake level (UL) are considered as drug". Both of these ingredients are fall below RDA. (RDA Level of calcium for adult is 300-1300 mg and vitamin D3 is 15 mcg) • Latest GMP inspection report not old then three years is required.
	Decision: Deferred, as both the ingredients used in the formulation are below RDA Level and accordingly not fall under the category of drug as per approved vitamin policy.	
2472.	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot # 129, sunder estate, Raiwind road Lahore
	Brand Name +Dosage Form + Strength	Grofast Suspension
	Diary No. Date of R& I & fee	Dy No.1309 ,24-6-14, Rs.20000/-
	Composition	Each 5ml contains: - Vitamin-D ……400 IU Ossein Mineral Complex….400 mg
	Pharmacological Group	Vitamin and calcium phosphorus supplement
	Type of Form	Form-5
	Finished Product Specification	Innovator Specs

	Pack size & Demanded Price	120 ml As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator.	Firm has submitted following: • Section approval was provided for general syrup section. • Cosmocol-D by Caraway Pharmaceutical is claimed to be reference but the strength is different. Not found in reference authorities
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and me-too status as stated reference is incorrect.
	Evaluation by PEC (AD PEC-XII)	Me-Too product Osnate –D suspension registered in the name of M/s. AGP Ltd., Karachi (Reg.no. 070854) Firm provide the evidence of letter of FID in which the officer verified the availability of atomic absorption spectrophotometer vide letter no. 12314/2017-DRAP (L-I) dated 15-09-2017.
	Decision: Deferred for the submission of complete composition of Ossein Mineral Complex by the firm.	
2473.	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot # 129, sunder estate, Raiwind road Lahore
	Brand Name +Dosage Form + Strength	D-Care Injection
	Diary No. Date of R& I & fee	Dy No. 1305, 24-6-2014, Rs. 20000/-
	Composition	Each ml contains: - Ergocalciferol (D2) BP….300,000 IU (7.5 mg)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished Product Specification	BP Specs
	Pack size & Demanded Price	1-amp x 2ml Rs.170.00/-
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not Provided
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator.	Evidence of reference both international and me too not found
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and me-too status as stated reference is incorrect.
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of approval of product in MHRA (UK) with the name of medicinal product Ergocalciferol Injection BP 300,000IU.
	Decision: Deferred for submission of application on Form 5D and fee.	
2474.	Name and address of manufacturer / Applicant	**M/s Cibex Pvt. Ltd. Factory # 405, SITE, Karachi.**

	Brand Name +Dosage Form + Strength	Cibex Calcium (Lemon flavor)
	Diary No. Date of R& I & fee	Dy No. 593, 30-4-2014, Rs.20000/-
	Composition	Each sachet contains: Calcium lactate gluconate…….1gm Calcium carbonate.327mg Ascorbic acid….500mg Vit D3…….4 mg Vit. B6…….10 mg
	Pharmacological Group	Calcium supplement
	Type of Form	Form-5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	10's As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not available
	Me-too status	Not available
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 21.05.2019.
	Remarks of the Evaluator.	• International reference need verification, given reference Poly Cal 500 by Polyfine Chempharma (not same), Me-too reference Pluc plus also don't have vitamin B6 so not same. • Latest report missing, and the presented one, just shows 2 functional sections of oral and liquid section. Firm also fail to obtain site change approval.
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for the evidence of approval, of applied formulation, by the reference regulatory authority and me-too status in.
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too Product is required as the provided evidence has not the same formulation. Further Sachet section approval letter is required.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and available in the market from past 5-7 years.** • **Evidence of Sachet section approval letter issued by Licensing Division/QA&LT Division.**	
2475.	Name and address of manufacturer / Applicant	M/s S.J&G. Fazul Ellahie (Pvt.) Ltd., E-46, S.I.T.E., Karachi
	Brand Name +Dosage Form + Strength	Joint Ease tablets
	Diary No. Date of R& I & fee	Duplicate Dossier, Rs. 20,000/- (08-01-2015)
	Composition	Each tablet contains: Alfacalcidol…….0.5 mcg Calcium carbonate…1000 mg (eq. to elemental calcium 400 mg)
	Pharmacological Group	Calcium, vitamin D
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specs.
	Pack size & Demanded Price	Rs. 150/10's,
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Oscal-D by Aries

	GMP status	Last inspection conducted on 12.01.17 with conclusive remarks of good level of GMP compliance.
	Remarks of the Evaluator.	• Firm has claimed Innovator's Specifications and submitted that the product is not available in any reference regulatory agency. • Firm has submitted the justification for 5% overage is to compensate the potency loss during shelf life.
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval of applied formulation by reference regulatory authorities and for inappropriate justification of overage.
	Evaluation by PEC (AD PEC-XII)	Both of these ingredients are fall below the RDA Level. Firm submitted their reply regarding the justification of overage in which they stated that "5% overage of Alfacalcidol + Calcium Carbonate has been added to compensate for any loss in potency during the storage period of 2 years (24 months). Further firm provide the evidence of Me-Too product Oscal-D Tablet registered in the name of M/s. Aries Pharmaceuticals Pvt. Ltd. (Reg.no. 073235)
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting as the formulation contain Alfacalcidol.	
2476.	Name and address of manufacturer / Applicant	M/s Nexus Pharmaceuticals 4/19-4/36 Sector 21 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Osen Plus Tablet
	Diary No. Date of R& I & fee	Dy. No. 311, 25-09-2014, Rs. 20,000/- (24-09-2014)
	Composition	Each film coated tablet contains: Ossein mineral complex ……830 mg Calcium…….177.6 mg Phosphorus ……82.2 mg Residual mineral salts….24.9 mg Collagen…….224.0mg Other proteins...66.4 mg F1, Mg, Fe, Zn, Cu, Ni corresponding to approximate hydroxyapatite….440 mg Vitamin D…….400 IU
	Pharmacological Group	Calcium supplements
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	Rs. 7.50 per tablet, Rs. 225/30's
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osnate D by AGP
	GMP status	Last inspection conducted on 13 &14 July, 2017 with conclusive remarks "Based on the areas inspected the people met and the documents reviewed, and considering the findings of the inspection M/s Nexus Pharma Pvt Ltd is considered at Satisfactory level of compliance with GMP guidelines as per Drug, Act,1976 and DRAP Act, 201 and rules framed thereunder."
	Remarks of the Evaluator.	….
	Previous Decision	Registration Board in it 269th meeting decided as

		under: Deferred for confirmation of approval status by reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of me-too product Osnate-D Tablet registered in the name of M/s. AGP Ltd., Karachi (Reg.no. 055948) • Firm provide the evidence of GMP inspection report dated 22-09-2015, wherein the area FID mentioned that the firm has recently purchased Atomic Absorption spectrophotometer.
	Decision: Deferred for the submission of latest GMP inspection report conducted during last 3 years.	
2477.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd Karachi.
	Brand Name +Dosage Form + Strength	Osmin-D Suspension
	Diary No. Date of R& I & fee	Diary No: 2749, 15/12/2016, Rs. 20,000/-
	Composition	Each 5ml of Suspension contains: Vitamin D…400 IU Ossein Mineral Complex….400 mg
	Pharmacological Group	Vitamin + Mineral
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specs.
	Pack size & Demanded Price	As per PRC As per PRC
	Approval status of product in Reference Regulatory Authorities.	International availability not mentioned.
	Me-too status	Osnate-D Suspension by M/s. AGP Ltd., Karachi.
	GMP status	GMP inspection conducted on 21-02-2019, concluded with the following remarks: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• International availability not confirmed. • Evidence of atomic absorption spectrophotometer confirmed Firm has claimed in house specs but not provided the following documents in the light of decision of 267th RB meeting □ Product and formulation development data □ Manufacturing method development and process validation □ Analytical method development and validation against innovator's analytical method and innovator's product □ Comparative pharmaceutical equivalence against innovator's product including comparative dissolution profiling • Stability data of the product for accelerated and real time period against innovator's product as a reference
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and

		detailed composition of ossein mineral complex.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Osnate-D Suspension registered in the name of M/s. AGP Ltd., Karachi (Reg. No. 070854) • Complete composition of ossein mineral complex is as under: Ossein Mineral Complex Corresponds to: Calcium…85.59 mg Phosphorus…39.61 mg Residual mineral salts…12 mg Collagen…107.95mg Other proteins…32 mg Trace Elements…Fl, Mg, Fe, Ni, Cu
	Decision: Deferred for confirmation of availability of Atomic Absorption Spectrophotometer for testing of these products.	
2478.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd Karachi.
	Brand Name +Dosage Form + Strength	Osmin Suspension
	Diary No. Date of R& I & fee	Diary No: 2748, 15/12/2016, Rs. 20,000/-
	Composition	Each 5ml of Suspension contains: Ossein Mineral Complex……..250 mg
	Pharmacological Group	Vitamin + Mineral
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specs.
	Pack size & Demanded Price	As per PRC As per PRC
	Approval status of product in Reference Regulatory Authorities.	International availability not mentioned.
	Me-too status	Osmin Suspension by M/s Himont Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-02-2019, concluded with the following remarks: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• International availability not confirmed. • Evidence of atomic absorption spectrophotometer confirmed Firm has claimed in house specs but not provided the following documents in the light of decision of 267th RB meeting □ Product and formulation development data □ Manufacturing method development and process validation □ Analytical method development and validation against innovator's analytical method and innovator's product □ Comparative pharmaceutical equivalence against innovator's product including comparative dissolution profiling • Stability data of the product for accelerated and real time period against innovator's product as a reference
	Previous Decision	Registration Board in its 269th meeting decided as under:

		Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and detailed composition of ossein mineral complex.
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Ossogin Suspension registered in the name of M/s. Himont Pharmaceuticals (Reg.no.031858) • Firm provide the complete composition of ossein mineral complex which is as under: Ossein Mineral Complex Corresponds to: Calcium….53.5 mg Phosphorus…24.75 mg Residual Mineral Salts….7.5 mg Collagen….67.46 mg Other proteins….20mg Trace elements…. (Fl, Mg, Fe, Zn, Cu & Ni)
	Decision: Deferred for confirmation of availability of Atomic Absorption Spectrophotometer for testing of these products.	
2479.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals, Pvt. Ltd. Karachi.
	Brand Name +Dosage Form + Strength	Mycalci-D Chewable Tablet
	Diary No. Date of R& I & fee	Dy.No.62 Rs.20,000/- dated 13-02-2014
	Composition	Each Chewable tablet contains: Calcium Carbonate 1250 mg eq. to Elemental calcium…500 mg Cholecalciferol 400IU eq. to Vitamin D3….10 mcg
	Pharmacological Group	Calcium and Vitamin D supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 100's As per PRC
	Approval status of product in Reference Regulatory Authorities.	…..
	Me-too status	OS- Cal chewable tablet by S.J.G. Fazal Ellahie Pharma
	GMP status	cGMP inspection report dated 02-07-2019 with the following conclusion: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remarks of the Evaluator.	Me-Too provided by the firm has not been verified.
	Previous Decision	Registration Board in its 268th meeting decided as under: Deferred for evidence of me-too status as reference submitted/provided is incorrect.
	Evaluation by PEC (AD PEC-XII)	• Evidence of Me-Too product which are already registered in Pakistan is required to be submitted by the firm or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. Further both of these ingredients are fall below RDA level. (RDA

		Level of calcium is 300-1300 in adults and vitamin D is 15mcg.
	Decision: Deferred for review for determining RDA Level in the light of decision of 295th meeting of Registration Board.	
2480.	Name and address of manufacturer / Applicant	**M/s Amarant Pharmaceuticals, Karachi.**
	Brand Name +Dosage Form + Strength	Facal-Ca Tablet
	Diary No. Date of R& I & fee	(Photocopy)Dy. No. 2210 Rs. 8000/-dated 21-12-2010 Rs.12,000/- dated 25-6-2014
	Composition	Each tablet contains: Alfacalcidol ….0.5 mcg Calcium carbonate eq. to elemental calcium…..500 mg
	Pharmacological Group	(Vitamin-Mineral)
	Type of Form	Form-5
	Finished Product Specification	Firm claimed Manufacturer specs
	Pack size & Demanded Price	30's As Per PRC
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Bone-Care-C by Schazoo zaka
	GMP status	GMP inspection report dated 24-07-2019 with the following conclusion: During inspection active production was seen mader way in Tablet (G) Capsule (G) and in Veterinary sections Up gradation is expected to be complied within next few months. After that firm would be able for inspection of grant of renewal of their DML & regularization of Lop. The firm was further advised to get the change made into approved Lop reapproved from the concerned division. Based on the above stated observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	• Rs. 8000, fee challan is not in original. • Me too status cannot be confirmed.
	Previous Decision	Registration Board in its 268th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities & me-too status and verification of fee challan of Rs. 8000/-
	Evaluation by PEC (AD PEC-XII)	*1.* Verification of fee challan of Rs. 8000/- is required. 2. Firm submitted its reply along with fee of Rs. 20,000 (dated 27-08-2020 Dy.no. 21676)with the new form-5, in which the firm has change the formulation according to the Me-Too product Oscal-D Tablet i.e. Each tablet contains: Alfacalcidol ….0.5 mcg Calcium carbonate eq. to elemental calcium….400 mg ***3.*** It is submitted that both the ingredients are below RDA.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as the formulation contain Alfacalcidol.	

2481.	Name and address of manufacturer / Applicant	**M/s Amarant Pharmaceuticals, Karachi.**
	Brand Name +Dosage Form + Strength	Amos 830 mg Tablet
	Diary No. Date of R& I & fee	(Photocopy) Dy No. 2212 Rs. 8000/- dated 21-12-2010 Rs.12,000/- dated 25-6-2014
	Composition	Each film coated tablet contains: Ossein Mineral Complex …830mg corresponds to: Calcium …….177.6mg Phosphorous ……82.2mg Residual Mineral Salts……. 24.9mg Collagen ….224mg Other Proteins….66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni Corresponding to approx. 440mg Hydroxyapatite
	Pharmacological Group	Calcium supplements
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	30's As Per PRC
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Intig 830 mg tab by Sami Pharmaceuticals
	GMP status	GMP inspection report dated 24-07-2019 with the following conclusion: During inspection active production was seen mader way in Tablet (G) Capsule (G) and in Veterinary sections Up gradation is expected to be complied within next few months. After that firm would be able for inspection of grant of renewal of their DML & regularization of Lop. The firm was further advised to get the change made into approved Lop reapproved from the concerned division. Based on the above stated observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	• Rs 8,000 fee challan is not in original. • International availability cannot be confirmed. • Me too (Intig) has residual mineral salts….24.8mg while Amos has 24.9mg • Atomic absorption spectrometer not present in the list. Firm claimed Manufacturer specs and the product is not present in available versions of USP 39 and BP 2016
	Previous Decision	Registration Board in its 268th meeting decided as under: Deferred for evidence of atomic absorption spectrophotometer and verification of fee challan of Rs. 8000/-
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Intig 830mg tablet registered in the name of M/s. Sami Pharmaceuticals (Reg.no.044331) • Firm provide purchase order invoice of Atomic Absorption Spectrophotometer.
	Decision: Deferred for the confirmation of availability of Atomic Absorption Spectrophotometer.	
2482.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals, Karachi.

	Brand Name +Dosage Form + Strength	Amos-D Tablet
	Diary No. Date of R& I & fee	(Photocopy) Dy No. 2213 Rs. 8000/- dated 21-12-2010 Rs.12,000/- dated 25-6-2014
	Composition	Each film coated tablet contains: Vitamin D……400 IU Ossein Mineral Complex …830 mg corresponding to: Calcium …….177.6 mg Phosphorous ……82.2 mg Residual Mineral Salts…24.9mg Collagen ….224mg Other Proteins…...66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni Corresponding to approx. 440mg Hydroxyapatite
	Pharmacological Group	Calcium supplements
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	30's As Per PRC
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Osnate-D tab by AGP
	GMP status	GMP inspection report dated 24-07-2019 with the following conclusion: During inspection active production was seen mader way in Tablet (G) Capsule (G) and in Veterinary sections Up gradation is expected to be complied within next few months. After that firm would be able for inspection of grant of renewal of their DML & regularization of Lop. The firm was further advised to get the change made into approved Lop reapproved from the concerned division. Based on the above stated observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator.	• Rs 8,000 fee challan is not in original. • International availability cannot be confirmed. • Me too (Osnate-D) has residual mineral salts….24.8mg while Amos-D has 24.9mg • Atomic absorption spectrometer not present in the list. Firm claimed Manufacturer specs and the product is not present in available versions of USP 39 and BP 2016
	Previous Decision	Registration Board in its 268th meeting decided as under: Deferred for evidence of atomic absorption spectrophotometer and verification of fee challan of Rs. 8000/-
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Osnate-D tablet registered in the name of M/s. AGP Ltd. (Reg.no. 055948) • Firm provide purchase order invoice of Atomic Absorption Spectrophotometer.
	Decision: Deferred for the confirmation of availability of Atomic Absorption Spectrophotometer.	
2483.	Name and address of manufacturer / Applicant	Dyson Research Laboratories Lahore Contract manufactured by English Pharma, Lahore

	Brand Name +Dosage Form + Strength	Dyalfa Injection 1mcg
	Diary No. Date of R& I & fee	Rs.8000.00 14-04-2010 Dy no.2418 Rs.50000/- dated 15-04-2013 Rs.42,000/- dated 25-04-2013
	Composition	Each ampoule contains: - Alfacalcidol …….1 mcg
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	As per SRO 10 x5mL
	Approval status of product in Reference Regulatory Authorities.	One Alpha Inj (MHRA) (Not present in 1mcg strength)
	Me-too status	Helpha Inj 1mcg by Hygeia Pharma. (Not present in 1mcg strength)
	GMP status	Panel inspection dated 11-01-2019 with the following conclusion: Recommendations: Panel inspected the unit and evaluated documents are connection with production, quality control and quality assurance. After thorough inspection of the manufacturing facility and evaluation of documents panel concluded that on the day of inspection firm has satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations. Copy of report handed over to the firm**.**
	Remarks of the Evaluator.	• Agreement for contract manufacturing issued on 16-01-2017. • Previously no product was being contract manufactured by English Pharma. • International availability and Me-too status cannot be confirmed. • Finish Product Specifications not provided.
	Previous Decision	Registration Board in its 268th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities & Me-too status.
	Evaluation by PEC (AD PEC-XII)	• Evidence of approval of applied formulation in reference regulatory agencies is required as it is required for injectable dosage form. • A finished product spec is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.	
2484.	Name and address of manufacturer / Applicant	M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Neuronit Tablets
	Diary No. Date of R& I & fee	Dy.No.1530&5069-7-6-12 Rs.8000/- dated 04-05-2012 Rs.12,000/- dated 15-07-2014
	Composition	Each tablet contains: - Vitamin B1 ……. 100 mg Vitamin B6 ……. 200 mg Vitamin B12 …..… 200 mcg

	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	10's, 20's, 30's; As Per SRO
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Neurobion Tablet by M/s. Martin Dow Marker Ltd.
	GMP status	Certificate of GMP Issued on 25-05-2019.
	Remarks of the Evaluator.	□ Firm has submitted printout of a webpage of M/s Merck Consumer Health Holding GmbH, Germany. □ The printout presents the description of a product "Neurobion tablets" stating composition same as formulation applied. □ The printout has been verified from the said webpage
	Previous Decision	Registration Board in its 267th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Neurobion Tablet registered in the name of M/s. Martin Dow Marker Ltd. (Reg.no. 001486). • Finished product specs. required.
	Decision: Approved with innovator's specification	
2485.	Name and address of manufacturer / Applicant	M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Mekobal 500mcg Capsules
	Diary No. Date of R& I & fee	Dy.No.2693 Rs. 8000/-dated 04-06-2012 Rs. 12,000/-dated 28-07-2014
	Composition	Each capsule contains: - Mecobalamin …. 500 mcg
	Pharmacological Group	(Co-enzyme type Vitamin B12)
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack size & Demanded Price	2x10's 10x10's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	International availability not provided.
	Me-too status	Mecbin by M/s. Ferroza pharmaceutical.
	GMP status	Certificate of GMP Issued on 25-05-2019.
	Remarks of the Evaluator.	Reference product stated by firm is not found in any reference regulatory authority
	Previous Decision	263rd Meeting Registration Board held on 29-30th November, 2016 Deferred for evidence of approval of applied dosage form & strength (regulatory authorities' formulation) in reference Registration Board in its 267th meeting decided as under: Deferred for evidence of approval of applied dosage form & strength (formulation) by reference regulatory authorities as stated reference is incorrect
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.

	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2486.	Name and address of manufacturer / Applicant	M/s Zanctok, Plot # F/5, SITE Hyderabad.
	Brand Name +Dosage Form + Strength	Calcirol Drops
	Diary No. Date of R& I & fee	Dy No. 495 Rs.8000/- Rs.12,000/- dated 2-4-2015
	Composition	Each ml contains: - Cholecalciferol ……400 IU/ml
	Pharmacological Group	(Vitamin D)
	Type of Form	Form 5
	Finished Product Specification	Mfg. Spec.
	Pack size & Demanded Price	10ml As per PRC
	Approval status of product in Reference Regulatory Authorities.	Provided evidence has not been verified.
	Me-too status	Provided evidence has not been verified.
	GMP status	GMP inspection report dated 30-08-2016 shows that firm is operating at acceptable level of GMP
	Remarks of the Evaluator.	Fultium-D_3 Drops by Internis Pharma UK MHRA contains cholecalciferol 2740 IU/ml. D4U by Genix Pharma contains cholecalciferol 40 IU/ml.
	Previous Decision	Registration Board in its 267th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities & me-too status for applied dosage form & strength.
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2487.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, Rawalpindi
	Brand Name +Dosage Form + Strength	Boost-D Suspension
	Diary No. Date of R& I & fee	Dy.No.1980 dated 27-03-2015 Rs.12 ,000/- Rs.8000/- dated 25-03-2015
	Composition	Each 5ml contains: - Ossein Mineral Complex…250 mg Vitamin-D …400 IU
	Pharmacological Group	(Minerals + Vitamin-D Supplement)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Mfg. Specs and the product is not present in available versions of BP and USP (B.P 2013 & USP 39)
	Pack size & Demanded Price	60 ml Rs.120
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Bonmin by S.J. & G Fazul Ellahie
	GMP status	GMP inspection report dated 14-12-2017 with the following conclusion:

	Remarks of the Evaluator.	•Reference Authority status could not be confirmed •Atomic absorption is given in equipment list.
	Previous Decision	Registration Board in its 266th meeting decided as under: Deferred for submission of complete formulation of Ossein Mineral complex
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of Me-Too Bonmin Suspension registered in the name of M/s. S.J.&G Fazul Ellahie (Reg.no. 070531). Complete composition of ossein mineral complex is required.
	Decision: Deferred for the submission of complete composition of Ossein Mineral Complex by the firm.	
2488.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, Rawalpindi
	Brand Name +Dosage Form + Strength	Dvit 1µg Injection
	Diary No. Date of R& I & fee	Dy.No.1972 dated 27-03-2015 Rs. 8000/- Rs.12,000/- dated 25-03-2015
	Composition	Each ml contains: - Cholecalciferol (BP)……1µg
	Pharmacological Group	(Vitamin D Analogue)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Mfg. Specs and the product is not present in available versions of BP and USP (B.P 2013 & USP 39)
	Pack size & Demanded Price	60 ml Rs.120
	Approval status of product in Reference Regulatory Authorities.	Clacijex in USA, EU
	Me-too status	Calcijex by Abbott Pharma Bonky by RG Pharma
	GMP status	GMP inspection report dated 14-12-2017 with the following conclusion:
	Remarks of the Evaluator.	• The SRA and Me too provided are that of calcitriol which is 1, 25-dihydroxycholecalciferol (vitamin D). • SRA and Me too in this strength not found. (1mcg/ml) • Firm has claimed Mfg. Specs and the product is not present in available versions of BP and USP (B.P 2013 & USP 39)
	Previous Decision	Registration Board in its 266th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities & me-too status as stated reference is not correct
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	

2489.	Name and address of manufacturer / Applicant	M/s. Medisave Pharma Lahore
	Brand Name +Dosage Form + Strength	Pevit 120m Syrup
	Diary No. Date of R& I & fee	Dy No. 358 Rs. 8000/- dated 04-06-2012 12000/- dated 19-11-2014
	Composition	Each 5ml contains: - Pizotifen maleate eq. to pizotifen…0.25mg Vitamin B1….0.875mg Riboflavin Phosphate…1.31mg Vitamin B6….0.77mg Nicotinamide……5.25mg
	Pharmacological Group	Appetite stimulant /vitamin
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Manufacturer Specification
	Pack size & Demanded Price	120ml As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Mosegor -V by Novartis Pharma Cestonil plus by Raazee Pharma
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	•Evidence of approval in reference regulatory authorities is not confirmed
	Previous Decision	Registration Board in its 265th meeting decided as under: Deferred for evidence of approval of applied formulation by reference regulatory authorities & clarification for indications
	Evaluation by PEC (AD PEC-XII)	Evidence of approval in reference regulatory agency is required as the vitamin formulation contain drug substance pizotifen.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2490.	Name and address of manufacturer / Applicant	**M/s. Dr. Raza Pharma, Peshawar**
	Brand Name +Dosage Form + Strength	Nervigor-Plus Capsules
	Diary No. Date of R& I & fee	Dy No. 20 Rs.8000/-dated 8-3-2011 Rs.12000/-dated 14-1-2015
	Composition	Each capsule contains: - Exsiccated Ferrous Sulphate…100mg (Eq. to elemental iron…32.5mg) Vitamin B1 …….2mg Vitamin B2 ……2mg Vitamin B6……1mg Vitamin C ……50mg Folic Acid ……...0.50mg Nicotinamide …….10mg
	Pharmacological Group	(Multivitamin + Iron)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Manufacturer Specification
	Pack size & Demanded Price	3× 20's

		Rs. 75
	Approval status of product in Reference Regulatory Authorities.	Not provided.
	Me-too status	Actifer by Polyfine
	GMP status	GMP inspection report dated 24, Jan,2019 concluded with the following remarks: Overall the GMP compliance is satisfactory.
	Remarks of the Evaluator.	Evidence of approval in reference regulatory authorities is not confirmed
	Previous Decision	Registration Board in its 265th meeting decided as under; Deferred for evidence of approval of applied formulation by reference regulatory authorities**.**
	Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too product Actifer capsule registered in the name of M/s. Polyfine Chempharma, Peshawar (reg.no. 041614) • Quantity of elemental iron used in the formulation is within the UL level according to the CRN (council for responsible nutrition) and USIOM (US institute of medicine) while the quantity used has been fall above UL level according to the UKSVM (UK Expert Group on vitamin and mineral) and Japan. (need discussion)
	Decision: Deferred for review of formulation as per decision taken in 295th meeting.	
2491.	Name and address of manufacturer / Applicant	M/s. Genome Pharmaceuticals, Hattar
	Brand Name +Dosage Form + Strength	Serofol 7.5mg Tablets
	Diary No. Date of R& I & fee	Dy No. 489 Rs. 8000/- dated 24-6-2011 Rs. 12,000/-dated 26-11-2014
	Composition	Each tablet contains: - L-Methyl folate Calcium…….7.5mg
	Pharmacological Group	mineral supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved (not verified)
	Me-too status	Keplin by Genetics (not verified)
	GMP status	GMP inspection report dated 12/05/18 with the following conclusion: **Conclusion:** "The firm has all the required facilities in production and quality control as per CGMP requirements, they have also maintained their documents of production procedure and QC analysis. The raw material facilities and dispensing facilities found maintained as per requirement. The firm has sufficient space for packing material and finished products. The hygienic condition of the worker found satisfactory. The documents and SOPs of production and QC found maintained. The firm has also established R&D section with highly

		equipped quality control and lab scale manufacturing equipment. The firm has also installed new double layered tablet manufacturing machine. Overall the firm was operating under Good level of cGMP."
	Remarks of the Evaluator.	Evidence of approval of the product in reference regulatory authorities cannot be confirmed
	Previous Decision	Registration Board in its 265th meeting decided as under: Deferred for the confirmation of approval in reference regulatory authorities
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2492.	Name and address of manufacturer / Applicant	M/s. Genome Pharmaceuticals, Hattar
	Brand Name +Dosage Form + Strength	Serofol 15mg
	Diary No. Date of R& I & fee	Dy No. 489 Rs. 8000/- dated 24-6-2011 Rs. 12,000/-dated 26-11-2014
	Composition	Each tablet contains: - L-Methylfolate Calcium…….15mg
	Pharmacological Group	folate mineral supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved (not verified)
	Me-too status	Deplin by Amarant (not verified)
	GMP status	GMP inspection report dated 12/05/18 with the following conclusion: Conclusion: "The firm has all the required facilities in production and quality control as per CGMP requirements, they have also maintained their documents of production procedure and QC analysis. The raw material facilities and dispensing facilities found maintained as per requirement. The firm has sufficient space for packing material and finished products. The hygienic condition of the worker found satisfactory. The documents and SOPs of production and QC found maintained. The firm has also established R&D section with highly equipped quality control and lab scale manufacturing equipment. The firm has also installed new double layered tablet manufacturing machine. Overall the firm was operating under Good level of cGMP."
	Remarks of the Evaluator.	Evidence of approval of the product in reference regulatory authorities cannot be confirmed
	Previous Decision	Registration Board in its 265th meeting decided as under: Deferred for the confirmation of approval in reference regulatory authorities

	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2493.	Name and address of manufacturer / Applicant	M/s. Friends Pharma, Lahore
	Brand Name +Dosage Form + Strength	Complex Injection 2ml
	Diary No. Date of R& I & fee	Dy No. 419 Rs. 8,000/- dated 4-12-2014 12000 dated 04-12-2014
	Composition	Each ml ampoule contains: - Thiamine hydrochloride ….10mg Riboflavin ….2mg Nicotinamide ….75mg Pyridoxine Hydrochloride ….5mg D-sodium Pantothenate ….5mg
	Pharmacological Group	Vitamin Formulation
	Type of Form	Form 5
	Finished Product Specification	Firm claimed Mfg. specification
	Pack size & Demanded Price	25 Ampoule*2ml as per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Mendozaplex Injection by Chas a Mendoza Ltd
	GMP status	GMP inspection report dated 08-03-2019 with the following conclusion: Conclusion: Overall the Evaluation of Inspection report is Good.
	Remarks of the Evaluator.	Evidence of approval of the product in reference regulatory authorities
	Previous Decision	Registration Board in its 265th meeting decided as under: Deferred for the confirmation of approval in reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	For injectable dosage form evidence of approval of formulation in reference regulatory agencies is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2494.	Name and address of manufacturer / Applicant	Focus & Rulz Pharmaceuticals (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Fotaz V Syrup
	Diary No. Date of R& I & fee	Dy.No.1024-STO(DRAP) dated 06-01-2011 Rs.8000/- Rs.12,000/- Fee adjusted on 9-1-2014
	Composition	Each 5ml contains: - Pizotifen (as Hydrogen Maleate...0.25mg Pyridoxine HCl USP... 0.77mg Nicotinamide USP…. 5.25mg Riboflavin Phosphate BP….1.31mg Thiamine HCl USP…. 0.88mg
	Pharmacological Group	(Appetite Enhancers + Vitamins)

	Type of Form	Form 5
	Finished Product Specification	Firm claimed Mfg. specification
	Pack size & Demanded Price	120ml as per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Mosegor V Syrup by Novartis
	GMP status	Renewal of DML inspection has conducted on 15-01-2019 & 17-01-2019 with the following conclusion: Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator.	• Differential fee of Rs 12000/ is adjusted according to the letter No. F.6-5/2015-Reg.III (24th Oct 2016) by Assistant Director (R-III) • Syrup section approval letter is attached
	Previous Decision	Registration Board in its 265th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities
	Evaluation by PEC (AD PEC-XII)	Evidence of approval in reference regulatory agency is required as the vitamin formulation contain drug substance pizotifen.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2495.	Name and address of manufacturer / Applicant	Tabros Pharma Karachi.
	Brand Name +Dosage Form + Strength	OSMIN D Tablet
	Diary No. Date of R& I & fee	Dy No.1152-A 07-05-2011 Rs.8000/-,20-11-2014 Rs.12,000/-
	Composition	Each film coated tablet contains; - Vitamin D…. 400 IU Ossein Mineral Complex……830mg Corresponding to: Calcium …177.6 mg Phosphorus ….82.20 mg Residual Mineral Salt….24.90 mg Collagen.224 mg Other Protein …….66.40 mg Trace Elements. F1, Mg, Fe, Zn, Cu, Ni Corresponding to Approx. 440mg Hydroxyapatite
	Pharmacological Group	Calcium Supplement
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specs
	Pack size & Demanded Price	3x10's Rs. 300.00
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Bonmin by S.J. & G. Fazul Ellahie Pharma, Karachi

	GMP status	GMP inspection report dated 07/02/18 with the following conclusion: "On the basis of current inspection, it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 264th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities and confirmation of atomic absorption spectrophotometer
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of Me-Too product Bonmin Tablet registered in the name of M/s. S.J. & G. Fazul Ellahie, Karachi (Reg.no.070532) Firm provide the evidence of GMP inspection report dated 02-12-2009 in which the Area FID endorsed that the firm has Atomic Absorption Spectrophotometer.
	Decision: Approved with innovator's specification.	
2496.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Karachi.
	Brand Name +Dosage Form + Strength	Osmin-D Suspension
	Diary No. Date of R& I & fee	Dy.No.1152 14-06-2012 Rs.8000/- Rs.12,000/- 20-11-2014
	Composition	Each 5ml contains: Vitamin D …….400 IU Ossein mineral complex …250mg Corresponding to calcium …53.50mg Phosphorus …….24.80 mg Residual mineral salts.7.50 mg Collagen …….67.50 mg Other proteins ……20.00 mg Trace elements F1, Mg, Fe, Zn, Cu & Ni)
	Pharmacological Group	Calcium Supplement
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specs
	Pack size & Demanded Price	60ml
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Ossobon-D by M/s. Platinum Pharma, Karachi
	GMP status	GMP inspection report dated 07/02/18 with the following conclusion: "On the basis of current inspection, it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 264th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities and confirmation of atomic absorption spectrophotometer
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of Me-Too product Ossobon-D Suspension registered in the name of M/s. Platinum Pharmaceuticals Karachi (Reg.no. 044004) Firm provide the evidence of GMP inspection report dated 02-12-2009 in which the Area FID endorsed that the firm has Atomic Absorption Spectrophotometer.

	Decision: Approved with innovator's specification.	
2497.	Name and address of manufacturer / Applicant	M/s Aims Pharmaceuticals Islamabad
	Brand Name +Dosage Form + Strength	Ferocare Chewable Tablets
	Diary No. Date of R& I & fee	Dy.No.1156 Rs. 8000/-dated 24-02-2015 Rs. 12,000/- dated 25-02-2015
	Composition	Each Chewable tablet contains: - Ferrous bisglycinate Chelate (eq. to Elemental Iron 27 mg) ... 158 mg Vitamin C …. 50 mg Folic Acid….200 mg Vitamin B 12..…. 0.1 mcg
	Pharmacological Group	Calcium Supplement
	Type of Form	Form-5
	Finished Product Specification	Mfg. Specs
	Pack size & Demanded Price	60ml
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	……..
	GMP status	Renewal of DML inspection conducted on "On the basis of current inspection, it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator.	…..
	Previous Decision	Registration Board in its 264th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities and confirmation of atomic absorption spectrophotometer
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too product is required which is registered and available in market from past 5-7 year.
	Decision: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new composition, evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2498.	Name and address of manufacturer / Applicant	M/s. Welmark Pharmaceuticals, Hattar
	Brand Name +Dosage Form + Strength	Welniacin Injection
	Diary No. Date of R& I & fee	Rs.8000/- Dated 28-2-2011 Rs.12000/- dated 30-12-2014
	Composition	Each 1ml contains: - Niacin (Vitamin B3) ……100 mg
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per SRO 1ml
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	Renewal of DML inspection conducted on 04-09-2018 & 26-09-2018 with the following conclusion: Conclusion:

		As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK
	Remarks of the Evaluator.	Evidence for Me-Too and international availability could not be confirmed
	Previous Decision	Registration Board in its 264th meeting decided as under: Deferred for evidence of approval by reference regulatory authorities & me-too status
	Evaluation by PEC (AD PEC-XII)	**For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.**
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2499.	Name and address of manufacturer / Applicant	**M/s. Weather Folds Pharmaceuticals, Hattar**
	Brand Name +Dosage Form + Strength	Lovaza 1000 mg Capsule
	Diary No. Date of R& I & fee	29-12-2010 Dy No. 44 Rs. 8000/ Rs. 12000/ dated 17-11-2014
	Composition	Each capsule contains: - Tocopherol (vitamin E) ….6.7 mg Omega-3-Acid Ethyl Esters….1000 mg
	Pharmacological Group	lipid-regulating agent +Vitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack size & Demanded Price	45's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Evidence of approval of formulation in Reference drug agencies is not provided.
	Me-too status	Not Provided
	GMP status	GMP inspection conducted on 15-09-2017 with the following conclusion: **Conclusion:** Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	Evidence of approval status in reference regulatory authorities is required
	Previous Decision	Registration Board in its 263rd meeting decided as under: Deferred for comments of Health & OTC Division regarding enlistment of applied formulation
	Evaluation by PEC (AD PEC-XII)	Evidence of approval of formulation in reference regulatory agencies is required as the formulation contain lipid regulating agent along with vitamin E.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2500.	Name and address of manufacturer / Applicant	Harrison Pharmaceuticals 10-Km, Lahore Road, Sargodha
	Brand Name +Dosage Form + Strength	Leon Syrup
	Diary No. Date of R& I & fee	Dy.no.: 1427 dated 13-10-16 of Rs. 20,000
	Composition	Each 5ml syrup contains: -

		L-Ornithine L-Aspartate…300mg/5ml, Nicotinamide….24mg/5ml, Riboflavin (Vitamin B2) ….0.153mg/ml
	Pharmacological Group	Vitamin and amino acid Supplement
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specification
	Pack size & Demanded Price	Pack of bottle 120ml as per PRC
	Approval status of product in Reference Regulatory Authorities.	Germany L-OrnithineL-Aspartate:300mg/5ml, Nicotinamide:24mg/5ml, Riboflavin (Vitamin B2):0.153mg/ml – MERZ Pharma GmbH
	Me-too status	Hepa-Merz by Brookes Pharmaceuticals
	GMP status	Inspection dated 31-3-16 for grant of new section and renewal of DML
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 263rd meeting decided as under: Deferred for evidence of approval in reference regulatory authorities
	Evaluation by PEC (AD PEC-XII)	Evidence of me-Too provided by the firm has not the same composition. GMP inspection report of not older than three years is required.
	Decision: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new composition evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting. Further copy of latest GMP inspection report not older than three years is required.	
2501.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt. Ltd. F-423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Bar-D Oral Drops
	Diary No. Date of R& I & fee	Dy.No. 632 dated 10-1-2014 of Rs. 20,000/-
	Composition	Each ml contains: Cholecalciferol (Vitamin D3) USP…….5 mg
	Pharmacological Group	Group of fat-soluble secosteroids responsible for enhancing intestinal absorption of calcim and phosphate
	Type of Form	Form 5
	Finished Product Specification	Manufacturers Specs
	Pack size & Demanded Price	Rs.450/10ml
	Approval status of product in Reference Regulatory Authorities.	Baby-D drops by Carlson Lab (USA) (not verified)
	Me-too status	Me-too required
	GMP status	GMP inspection conducted on 16th-28th Aug, 2018 concluded with the following remarks: Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 262nd meeting decided as under: Deferred for confirmation of approval status in reference regulatory authorities & me-too status.

	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting.	
2502.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Islamabad
	Brand Name +Dosage Form + Strength	Come-Vit Sachet
	Diary No. Date of R& I & fee	Rs.8000/-27-06-2012 Rs.12,000/ 12.03.2013
	Composition	Each sachet contains: - Ascorbic Acid USP…….100mg Nicotinamide USP…….50mg Riboflavin (Riboflavin-5PhosphateUSP…….15mg Pyridoxine HCl USP….10mg Thiamine Hydrochloride USP……15mg Calcium glycerophosphate USP…….373.3mg Calcium Carbonate USP …100mg Calcium Pantothenate USP…15mg Eq. to total Elemental Calcium….134.64mg
	Pharmacological Group	Vitamin &Mineral Formulation
	Type of Form	Form 5
	Finished Product Specification	Manufacturers Specs
	Pack size & Demanded Price	10's Sachet As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	GMP inspection conducted on 17-05-2019 concluded with the following remarks: Overall Evaluation of the Inspection Report is rated as Good.
	Remarks of the Evaluator.	….
	Previous Decision	Registration Board in its 261st meeting decided as under: Deferred product for vitamin policy.
	Evaluation by PEC (AD PEC-XII)	Evidence of me-Too product registered in Pakistan from past 5-7 years is required. Quantity of Base form of element is required for determination of UL Level.
	Decision: Deferred for the submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and available in the market from past 5-7 years. In case of new composition evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.** • **Quantity of Base form of element/mineral is required for determination of UL Level.**	
2503.	Name and address of manufacturer / Applicant	**M/s Hilton Pharma (Pvt.) Ltd, 13, Sector 15, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Hilto-D Sachet

	Diary No. Date of R& I & fee	Rs 50,000 vide Dy # 1408 dated 19-07-2013
	Composition	Each Sachet contains Vitamin D3 (Cholecalciferol)….600,000 IU
	Pharmacological Group	Vitamin &Mineral Formulation
	Type of Form	Form 5D
	Finished Product Specification	Manufacturers Specs
	Pack size & Demanded Price	Pack size 30s → Rs. 900/-
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	GMP inspection conducted on 10-07-2019 concluded with the following remarks: Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Hilton Pharma, it was concluded that M/s Hilton Pharma is operating at a good level of CGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	Firm needs to provide following documents / information for completion of application. Proof of approval status of same dosage form in reference countries
	Previous Decision	Registration Board in its 260th meeting decided as under: Deferred for confirmation of approval status of same formulation / dosage form by reference regulatory authorities.
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2504.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories (Private) Limited, 21-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Tablet Vital
	Diary No. Date of R& I & fee	08-09-2010 Rs.8000/- 30-7-2013 Rs. 12000/- ***(Photocopy)***
	Composition	Each film coated tablet contains Vitamin A (Acetate) USP 5000 I.U Vitamin C (Ascorbic Acid) BP 500mg Vitamin E USP 200 I.U Vitamin D (Cholecalciferol D3) USP 100 I.U Folic Acid BP 200 mcg Vitamin B1 (Thiamine mononitrate) USP 15mg Vitamin B2 (Riboflavin) USP 15mg Zinc BP 40mg Copper BP 2mg Manganese BP 1.5mg Selenium BP 40.5mcg
	Pharmacological Group	Vitamin &Mineral Formulation
	Type of Form	Form 5
	Finished Product Specification	Manufacturers Specs
	Pack size & Demanded Price	Pack size of

		30s → Rs. 510/-
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Occulovit – Ethical Laboratories (Not Verified)
	GMP status	Renewal of DML inspection was conducted on 13.09.2019 concluded with the following remarks: The panel of inspector recommends the renewal of M/s Pharmix Laboratories Pvt Ltd. Located at 21 Km, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad.
	Remarks of the Evaluator.	….
	Previous Decision	Registration Board in its 260th meeting decided as under: Deferred for confirmation of approval status by reference regulatory authorities, vitamin policy and fee challan
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too Product registered in Pakistan from past 5-7 years is required further evidence of submission of registration application is required for verification**.**
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new composition evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.	
2505.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories (Private) Limited, 21-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Tablet Vitamax
	Diary No. Date of R& I & fee	30-9-2010 Rs.8000/- 30-7-2013 Rs. 12000/- (***Photocopy)***
	Composition	Vitamin A (Acetate) USP 10mg Vitamin C (Ascorbic acid) USP 60mg Vitamin E USP 30mg Vitamin D (Cholecalciferol D3) USP 10 mcg Folic Acid USP 0.400mg Vitamin B1 (Thiamine mononitrate) USP 1.50mg Vitamin B2 (Riboflavin) USP 1.70mg Vitamin B6 (Pyridoxine) USP 2 mg Vitamin B12 (Cyanocobalamin) USP 6 mcg Niacin USP 20mg Pantothenic acid USP 10mg D-Biotin USP 30 mcg Calcium USP 130mg Phosphorus USP 100mg Iodine USP 150 mcg Iron USP 18 mg Magnesium USP 100mg Copper USP 2mg Zinc USP 15mg Potassium USP 37.50mg Maganese USP 2.50mg Chromium USP 10 mcg Molybdenum USP 10 mcg Selenium USP 10 mcg Chloride USP 34 mg
	Pharmacological Group	Vitamin &Mineral Formulation
	Type of Form	Form 5

	Finished Product Specification	Manufacturers Specs
	Pack size & Demanded Price	Pack size of 30s → Rs. 390/-
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Once a Day – CCL
	GMP status	Renewal of DML inspection was conducted on 13.09.2019 concluded with the following remarks: The panel of inspector recommends the renewal of M/s Pharmix Laboratories Pvt Ltd. Located at 21 Km, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad.
	Remarks of the Evaluator.	….
	Previous Decision	Registration Board in its 260th meeting decided as under: Deferred for confirmation of approval status by reference regulatory authorities, vitamin policy and fee challan
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too Product registered in Pakistan from past 5-7 years is required as the provided evidence of Me-Too has different composition; further evidence of submission of registration application is required for verification.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
2506.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad
	Brand Name +Dosage Form + Strength	Doplet-3 400IU Oral Drops Composition
	Diary No. Date of R& I & fee	Dy.No.21230 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Composition	Each drop Contains: Cholecalciferol (Vitamin D3) …400IU
	Pharmacological Group	Vitamin-D
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml,15ml,20ml: Rs.1500/-, Rs.2000/-, Rs.3000/-
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML conducted on 13-10- 2017 recommended renewal of DML BEARING No.00616

Remarks of the Evaluator.

Remarks	Response
Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	Sapvit-D 400 IU/ drops of MHRA
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	D-4U Drops of Genix Pharma (as provided by the firm) Miura-D Drops of Getz Pharma (as provided by the firm, not verifiable) Calciferol Drops of Global Drops (as provided by the firm, not verifiable)

	Previous Decision	Deferred for the following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as formulation of provided generic is in milligrams/ml Registration Board in its 292nd meeting decided as under: Registration Board deferred the case for further deliberation whether it has to be considered in PE&R Division as drug or in HOTC Division as nutraceutical.
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of approval of formulation in MHRA Sapvit-D 400 IU/drops. Further according to the reference product each ml (36 drops) contain 14,400IU of vitamin D3 which is above the RDA level and in reference agency product is registered as drug with the intended therapeutic purpose i.e. for the treatment of • Prevention and treatment of vitamin D deficiency • Treatment of rickets • As an adjunct to a specific therapy for osteoporosis in patients at risk of vitamin D deficiency
	Decision: Deferred for submission of application on Form-5D alongwith differential fee.	
2507.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited, Plot #37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Combrix Syrup
	Diary No. Date of R& I & fee	19-03-2013 Rs. 20,000/-(Photocopy)
	Composition	Each 5ml contains Cyproheptadine Orotate……..1.5mg Carnitine Chlorhydrate……150mg Lysine Chlorhydrate (B.P) ……150mg Vitamin B1 (B.P) ……10mg Vitamin B6 (B.P) ……10mg Vitamin B12 (B.P) …….100mcg
	Pharmacological Group	Appetite Stimulant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Price As per SRO Pack Size: 60ml&120ml
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Tres-Orix Forte (Highnoon Laboratories)
	GMP status	Report dated 4-12-2018 with the following conclusion: Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator.	Fee Rs. 20, 000 is a photocopy. Approval status in reference countries is not provided.
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for the submission of following. Clarification of intended use of the applied formulation as appetite stimulant Approval status by reference regulatory authorities along with verification of fee. Registration Board has further directed to obtain written clarification from the firms who has already registered products

	Evaluation by PEC (AD PEC-XII)	Evidence of approval of formulation in reference regulatory agencies is required as the formulation contain Cyproheptadine Orotate which is antihistamine.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting.	
2508.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited, Plot #37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dowmetabol Syrup
	Diary No. Date of R& I & fee	19-03-2013 Rs.20,000/-(Photocopy)
	Composition	Each 15ml contains (After reconstitution) Metopine……2.75mg L-lysine ……...250mg DL-carnitine……...375mg Vitamin B1…….30mg Vitamin B6…….30mg Vitamin B12…….1000mcg
	Pharmacological Group	Appetite Stimulant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Price As per SRO Pack Size: 60ml &120ml
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Trimetabol (Sami Pharmaceuticals Pvt. Ltd)
	GMP status	Report dated 4-12-2018 with the following conclusion: Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator.	Fee Rs. 20,000 is a photocopy. Approval status in reference countries and Pakistan is not provided.
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for the submission of following. Clarification of intended use of the applied formulation as appetite stimulant Approval status by reference regulatory authorities along with verification of fee. Registration Board has further directed to obtain written clarification from the firms who has already registered products
	Evaluation by PEC (AD PEC-XII)	Metopine is an appetite stimulant range of this ingredient has not included in the approved UL Table.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2509.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Vitaglobin Plus Syrup
	Diary No. Date of R& I & fee	27-2-2013 Dy.No.166 Form 5 Rs.20,000/- *Photocopy*
	Composition	Each 5ml contains: Iron polymaltose complex iron……50.0 mg

		Folic Acid…0.5 mg Vitamin B1.1.0 mg Vitamin B6….2.0 mg Nicotinamide…10.0 mg Vitamin B12…18.0 mcg
	Pharmacological Group	(Anti Anemic)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Pack size of 90ml→Rs. 250/- 120ml→Rs. 300/- 250ml→Rs. 500/-
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	GMP inspection conducted on 18-10-2018 concluded with the following remarks: Conclusion: GMP compliance level is rated as GOOD."
	Remarks of the Evaluator.	Proof of approval status of same dosage form in Pakistan and reference regulatory authorities.
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for confirmation of approval by reference regulatory authorities and Pakistan.
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too product registered in Pakistan from past 5-7 years is required.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.	
2510.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited, Plot #37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aura-D 400 IU/5ml Syrup
	Diary No. Date of R& I & fee	29-08-2012 Dy.No.1439 Rs. 8,000/- ***(photocopy)*** Rs. 12,000/- 20-11-2013 Dy. No. 327
	Composition	Each 5ml contains: Cholecalciferol (USP)….. 400 IU
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Price As per SRO Pack Size: 10ml, 30ml, 60ml&120ml
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Not Provided
	GMP status	Report dated 4-12-2018 with the following conclusion: Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator.	Proof of approval status of same formulation in Pakistan and reference regulatory authorities.
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for confirmation of approval by reference regulatory authorities and Pakistan

	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required**.**
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2511.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited, Plot #37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aura-D 5000 IU Tablet
	Diary No. Date of R& I & fee	29-08-2012 Dy.No.1442 Rs. 8,000/- ***(photocopy)*** Rs. 12,000/- 20-11-2013 Dy. No. 327
	Composition	Each tablet contains: Cholecalciferol (USP)...…….. 5000 IU
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Price As per SRO Pack Size: 10’s, 20's, 30’s&60's
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Not Provided
	GMP status	Report dated 4-12-2018 with the following conclusion: Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator.	Proof of approval status of same formulation in Pakistan and reference regulatory authorities
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for confirmation of approval by reference regulatory authorities and Pakistan
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2512.	Name and address of manufacturer / Applicant	M/s Mission Pharmaceutical, Karachi
	Brand Name +Dosage Form + Strength	Fomag Bind Tablet
	Diary No. Date of R& I & fee	Dairy No. 142 dated 10-03-2016 Rs: 20,000/-
	Composition	Each film coated tablet contains: - Magnesium carbonate...400mg Calcium Carbonate.....200mg Folic Acid.....1mg
	Pharmacological Group	(Mineral, vitamin Supplement)
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	120ml/ Rs.45/-
	Approval status of product in Reference Regulatory Authorities.	Magne bind 400 RX Nephro-Tech Inc USA
	Me-too status	Me-too status is not confirmed
	GMP status	

	Remarks of the Evaluator.	Deferred in 257th meeting for availability in Pakistan. Me-too is not available in Pakistan.
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for submission of application on Form 5D and requisite fee
	Evaluation by PEC (AD PEC-XII)	Evidence of approval of formulation in reference regulatory agencies is required Further firm has to submit the application on Form 5D along with requisite fee as decided in previous meeting. Latest GMP inspection report not older than three years is required.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.	
2513.	Name and address of manufacturer / Applicant	**M/s Nexus Pharmaceuticals 4/19-4/36 Sector 21 Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Nexcee-P Sachet
	Diary No. Date of R& I & fee	Dy.No. 134 dated 23-2-2016 Rs:20,000/-
	Composition	Each sachet contains: Calcium lactate gluconate. 500mg Calcium carbonate….327 mg Calcium gluconate….587mg Calcium lactate….420 mg Vitamin C…….500 mg
	Pharmacological Group	(Vitamin and minerals)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not confirmed in SRA
	Me-too status	Me-too status is not confirmed
	GMP status	Last inspection conducted on 13 &14 July, 2017 with conclusive remarks "Based on the areas inspected the people met and the documents reviewed, and considering the findings of the inspection M/s Nexus Parma Pvt Ltd is considered at Satisfactory level of compliance with GMP guidelines as per Drug, Act 1976 and DRAP Act, 201 and rules framed thereunder."
	Remarks of the Evaluator.	Availability in SRA not confirmed and as Me-too
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for • rationality of Formulation • the firm may apply for registration of the said product on form 5-D.
	Evaluation by PEC (AD PEC-XII)	Evidence of approval of formulation in reference regulatory agencies is required as the Me-Too status has not confirmed. Further firm has to submit application on Form-5D along with requisite documents.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Incase Me-Too is not available than firm has to provide the evidence of approval of applied formulation in reference regulatory authorities/agencies	

	which were declared/approved by the Registration Board in 275th meeting, further firm has to submit the application on Form 5-D along with prescribe fee.	
2514.	Name and address of manufacturer / Applicant	M/s Nexus Pharmaceuticals 4/19-4/36 Sector 21 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Gluvit Sachet
	Diary No. Date of R& I & fee	Dy.No.132 dated 23-2-2016 Rs:20,000/-
	Composition	Each sachet contains: Calcium lactate gluconate……1000 mg Calcium carbonate….327 mg Vitamin C …….500 mg
	Pharmacological Group	(Antacid, antiosteoporosis)
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Availability in SRA is not confirmed
	Me-too status	Pluc Sachet by M/s Indus Pharma Karachi.
	GMP status	Last inspection conducted on 13 &14 July, 2017 with conclusive remarks "Based on the areas inspected the people met and the documents reviewed, and considering the findings of the inspection M/s Nexus Pharma Pvt Ltd is considered at Satisfactory level of compliance with GMP guidelines as per Drug, Act,1976 and DRAP Act, 201 and rules framed thereunder."
	Remarks of the Evaluator.	Availability in SRA not confirmed
	Previous Decision	Registration Board in 259th meeting decided as under: Deferred for • confirmation of approval status by reference regulatory authorities and Pakistan status • Confirmation of indications
	Evaluation by PEC (AD PEC-XII)	Firm provide the evidence of Me-Too product Pluc Sachet registered in the name of M/s. Indus Pharma Karachi (Reg.no. 039613) CaC-1000 Sachet of M/s. GSK Consumer Healthcare (Reg.no.084643).
	Decision: Approved with innovator's specification.	
2515.	Name and address of manufacturer / Applicant	M/s Nexus Pharmaceuticals 4/19-4/36 Sector 21 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Chalenex sachet
	Diary No. Date of R& I & fee	Dy.No.129 dated 23-2-2016 of Rs:20,000/-
	Composition	Each gm sachet contains: Cholecalciferol (Vitamin D3) …….60000 IU
	Pharmacological Group	Vitamin D3
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Availability in SRA is not confirmed
	Me-too status	Me-too status is not confirmed
	GMP status	Last inspection conducted on 13 &14 July, 2017 with conclusive remarks "Based on the areas inspected the people met and the documents reviewed, and considering the findings of the inspection M/s Nexus Pharma Pvt Ltd is considered at Satisfactory level of compliance with GMP guidelines as per Drug, Act,1976 and DRAP Act, 201 and rules framed thereunder."

	Remarks of the Evaluator.	Availability in SRA is not confirmed Me-too status is not confirmed
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for confirmation of approval status by reference regulatory authorities and Pakistan
	Evaluation by PEC (AD PEC-XII)	For Single ingredient vitamin formulation evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting is required.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2516.	Name and address of manufacturer / Applicant	M/s Nexus Pharmaceuticals 4/19-4/36 Sector 21 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Otamin-D Dry powder suspension
	Diary No. Date of R& I & fee	Dy.No.126 dated 23-2-2016 Rs: 20,000/-
	Composition	Each 5ml contains: Vitamin D…….400 IU Ossein mineral complex corresponding to calcium…….250.0 mg Phosphorus……53.20 mg Residual mineral salts...28.40mg Collagen…….7.50mg Other proteins…….67.50mg Trace elements……20.00mg F, Mg, Fe, Zn, Cu, Ni corresponding to approximate….132.00mg
	Pharmacological Group	(Osteoporosis or calcium supplements)
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Availability in SRA is not confirmed
	Me-too status	Me-too status is not confirmed
	GMP status	Last inspection conducted on 13 &14 July, 2017 with conclusive remarks "Based on the areas inspected the people met and the documents reviewed, and considering the findings of the inspection M/s Nexus Pharma Pvt Ltd is considered at Satisfactory level of compliance with GMP guidelines as per Drug, Act, 1976 and DRAP Act, 2012 and rules framed thereunder."
	Remarks of the Evaluator.	Availability in SRA is not confirmed Me-too status is not confirmed
	Previous Decision	Registration Board in its 259th meeting decided as under: Deferred for confirmation of approval status by reference regulatory authorities and clarification for formulation
	Evaluation by PEC (AD PEC-XII)	Evidence of Me-Too registered in Pakistan from past 5-7 years is required
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new composition evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 277th meeting is required.	

<table>
<tr><td rowspan="12">2517.</td><td>Name and address of manufacturer / Applicant</td><td>M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>HIGH C-D Sachet (Orange Flavor)</td></tr>
<tr><td>Diary No. Date of R& I & fee</td><td>(Duplicate Dossier) Dy.188 No. dated 19/12/2008
Differential fee (Photocopy) of Rs.12,000/- submitted on 26/10/2017</td></tr>
<tr><td>Composition</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg
Vitamin B6….10mg</td></tr>
<tr><td>Pharmacological Group</td><td>Vitamin and mineral formulations</td></tr>
<tr><td>Type of Form</td><td>Form 5</td></tr>
<tr><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td>Pack Size & Demanded Price</td><td>As per S.R. O</td></tr>
<tr><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td>Me-too Status</td><td>CaC-1000 sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro</td></tr>
<tr><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td>Remarks of the Evaluator.</td><td>1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.</td></tr>
<tr><td>Previous Decision</td><td>Registration Board in its 295th meeting decided as under:
Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table>
It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent.</td></tr>
<tr><td colspan="2">Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.</td></tr>
</table>

<table>
<tr><td>2518.</td><td>Name and address of manufacturer / Applicant</td><td>M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>HIGH C-D Sachet (Lemon Flavor)</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No. 6423 dated 08/04/2020 Rs.20,000/-</td></tr>
<tr><td></td><td>Composition</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3 ….4mg
Vitamin B6….10mg</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Vitamin and mineral formulations</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td></td><td>Pack Size & Demanded Price</td><td>As per S.R.O & Pack: 10’s</td></tr>
<tr><td></td><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td></td><td>Me-too Status</td><td>CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro</td></tr>
<tr><td></td><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>1. Application is received on Form-5 instead of Form 5-F.
2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.</td></tr>
<tr><td></td><td>Previous Decision</td><td>Registration Board in its 295th meeting decided as under:
Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td></td><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table>
It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent. Further Registration application has received on Form-5 instead of Form 5-F.</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred for the submission of following:
• Submission of registration Application on Form 5-F (CTD Format)
• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
</table>

<table>
<tr><td></td><td colspan="2">In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.</td></tr>
<tr><td rowspan="12">2519.</td><td>Name and address of manufacturer / Applicant</td><td>M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad</td></tr>
<tr><td>Brand Name +Dosage Form + Strength</td><td>HIGH C-D Sachet (Mango Flavor)</td></tr>
<tr><td>Diary No. Date of R& I & fee</td><td>Dy. No. 6423 dated 08/04/2020 Rs.20,000/-</td></tr>
<tr><td>Composition</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3 ….4mg
Vitamin B6….10mg</td></tr>
<tr><td>Pharmacological Group</td><td>Vitamin and mineral formulations</td></tr>
<tr><td>Type of Form</td><td>Form 5</td></tr>
<tr><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td>Pack Size & Demanded Price</td><td>As per S.R.O & Pack: 10’s</td></tr>
<tr><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td>Me-too Status</td><td>CaC-1000 Sachet by M/s. GlaxoSmithKline OTC (Pvt.) Ltd., Petaro</td></tr>
<tr><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td>Remarks of the Evaluator.</td><td>Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
Application is received on Form-5 instead of Form 5-F.
Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.</td></tr>
<tr><td>Previous Decision</td><td>Registration Board in its 295th meeting decided as under: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table>
It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent. Further Registration application has received on Form-5 instead of Form 5-F.</td></tr>
</table>

<table>
<tr><td></td><td colspan="2">Decision: Deferred for the submission of following:
• Submission of registration Application on Form 5-F (CTD Format)
• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
• In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.</td></tr>
<tr><td>2520.</td><td>Name and address of manufacturer / Applicant</td><td>M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>HIGH C-D Sachet (Cola Flavor)</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No. 6423 dated 08/04/2020 Rs.20,000/-</td></tr>
<tr><td></td><td>Composition</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg
Vitamin B6….10mg</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Vitamin and mineral formulations</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td></td><td>Pack Size & Demanded Price</td><td>As per S.R.O & Pack: 10’s</td></tr>
<tr><td></td><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td></td><td>Me-too Status</td><td>CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro</td></tr>
<tr><td></td><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>1. Application is received on Form-5 instead of Form 5-F.
2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.</td></tr>
<tr><td></td><td>Previous Decision</td><td>Registration Board in its 295th meeting decided as under: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.</td></tr>
<tr><td></td><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table></td></tr>
</table>

		It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent. Further Registration application has received on Form-5 instead of Form 5-F.
	Decision: Deferred for the submission of following: • **Submission of registration Application on Form 5-F (CTD Format)** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.**	
2521.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No…. dated 19/12/2008 Rs.8,000/- Differential fee (Photocopy) of Rs.12,000/- submitted on 26/20/2017
	Composition	Each Sachet contains: Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R. O
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Previous Decision	Registration Board in its 295th meeting decided as under: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Response of the firm along with Remarks of the Evaluator	Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and Alcee-D Sachet which is as under:

CaC-1000 Plus Effervescent Tablet	Calcee-D Sachet
Each Effervescent tablet contains: Calcium Lactate Gluconate….1000mg	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg

		Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….400IU Vitamin B6….10mg | Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….4mg/400IU Vitamin B6….10mg It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.	
2522.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Lemon Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6417 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5-F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Previous Decision	Registration Board in its 295th meeting decided as under: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Response of the firm along with Remarks of the Evaluator	Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and Calcee-D Sachet which is as under: CaC-1000 Plus Effervescent Tablet | Calcee-D Sachet Each Effervescent tablet contains: | Each Sachet contains: Calcium Lactate Gluconate….1000mg

		<table><tr><td>Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..400IU Vitamin B6…..10mg</td><td>Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg/400IU Vitamin B6…..10mg</td></tr></table> It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent. Further Registration application has received on Form-5 instead of Form 5-F.
	Decision: Deferred for the submission of following: • **Submission of registration Application on Form 5-F (CTD Format)** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.**	
2523.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Cola Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6416 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator.	1. Application is received on Form-5 instead of Form 5F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Previous Decision	Registration Board in its 295th meeting decided as under: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Response of the firm along with Remarks of the Evaluator	Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and Calcee-D Sachet which is as under:

		CaC-1000 Plus Effervescent Tablet	Calcee-D Sachet
		Each Effervescent tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..400IU Vitamin B6…..10mg	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg/400IU Vitamin B6…..10mg
		It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent. Further Registration application has received on Form-5 instead of Form 5-F.	
	Decision: Deferred for the submission of following: • **Submission of registration Application on Form 5-F (CTD Format)** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.**		

Item No. I: Agenda of Evaluator PEC-III

Case no. 01 Registration applications for local manufacturing of (Human) drugs

a. Deferred cases

2524.	**Name and address of manufacturer / Applicant**	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Evolar 2.5mg Tablet
	Composition	Each film coated tablet contains: Everolimus…2.5mg
	Diary No. Date of R& I & fee	Dy No. 26865: 06-08-2018 PKR 20,000/-: 03-08-2018
	Pharmacological Group	Antineoplastic agent
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	30's, Rs. 10000/- per tablet
	Approval status of product in Reference Regulatory Authorities.	Everolimus 2.5mg Tablets by Synthon Hispania (**MHRA** Approved)
	Me-too status	Afinitor tablets by Novartis
	GMP status	Last GMP inspection report dated 31-8-2016 confirms satisfactory compliance to GMP.
	Remarks of the Evaluator[3]	• Justify the formulation of film coated tablet since the reference product is uncoated tablet, in case of revision of formulation as per the reference product requisite fee needs to be submitted.
	Decision of 286th meeting of Registration Board	Deferred for following submissions:

		• Revision of formulation to uncoated tablet as per the reference product along with submission of fee. • Updated GMP status of the firm from QA&LT Division
	Evaluation by PEC[3]	Firm has submitted the following • Revised master formulation and method of manufacturing for the uncoated tablets along with submission of fee PKR 20,000/- dated 17-08-2020 for revision of formulation • GMP inspection report dated 04-02-2020 in which the panel concludes satisfactory level of cGMP compliance. The panel further reported that since the firm had upgraded the layout of anti-cancer section, therefore the firm was advised to get the anticancer section regularized and approved by DRAP, Islamabad after fulfilment of all codal formalties.
	Decision: Registration Board deliberated the matter and decided to defer the case for confirmation of cytotoxic facility since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.	
2525.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by M/s English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Moripime 500mg Injection
	Composition	Each Vial Contains: Cefepime HCL with L-Arginine eq to Cefepime…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4607 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic-cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Feldopim 500mg Injection of M/s Wnsfeild (Reg.#046970)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2526.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore

		Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Moripime 1g Injection
	Composition	Each Vial Contains: Cefepime HCL with L-Arginine eq to Cefepime…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4609 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic-cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Nuxipim 1g Injection of Bosch
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2527.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Combact Injection 1g
	Composition	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4619 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by PMDA-Japan
	Me-too status	2Sum Injection 1g of Sami Pharma (R.#047002)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018

	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2528.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Combact Injection 2g
	Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4617 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Cebac 2 g Injection by M/s Bosch Pharma
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2529.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Bonigen Injection 200,000IU/ml
	Composition	Each ml contains: Vitamin D-3 Cholecalciferol …200,000IU
	Diary No. Date of R& I & fee	Form-5 Dy.No 4608 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Vitamin- D
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml glass ampoule: As per SRO

	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule & VITAMIN D3 GOOD 200,000 IU / 1 ml, oral solution in ampoule (**ANSM** France Approved)
	Me-too status	Drol- D injection by Regal Pharma (Reg. # 082005)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2530.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Gemton Injection 40mg/vial/IM
	Composition	Each Vial Contains: Esomeprazole as sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4612 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for Injection vial. (**TGA** approved)
	Me-too status	Somezol Injection 40mg by Bosch (Reg# 045386)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2531.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by

		English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Ferogem Injection 5ml
	Composition	Each 5ml contains: Iron Sucrose complex eq to Elemental Iron…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4616 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection (**TGA** Approved)
	Me-too status	Iroject Injection by Medley Pharma (Reg#070173)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2532.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Methicol Injection 500mcg
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4614 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Vitamin B-12
	Type of Form	Form 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	1ml ampoule x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Comezengen injection 500 µg of M/s Tatsumi Chemical (PMDA Japan Approved)
	Me-too status	Flench injection of Tabros Pharma (Reg. # 029050)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018

	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2533.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Myriva Infusion 400mg
	Composition	Each 250ml vial contains: Moxifloxacin as HCl…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4613 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle by M/s Bayer Australia Ltd (TGA Approved)
	Me-too status	Izilon I.V Infusion 400mg/250ml by Bosch (Reg#030074)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2534.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Safpep 40mg Injection
	Composition	Each Vial Contains: Omeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4604 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	Innovator's specs

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA Approved)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision of 295th meeting of Registration Board	• Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2535.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Zipbact 2.25g Injection
	Composition	Each Vial Contains: Piperacillin as sodium…2g Tazobactam as sodium…0.25g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4606 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin/Tazobactam 2 g/0.25 g Powder for Solution for Infusion (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/- • Evidence of approval of required manufacturing facility / section could not be confirmed.
	Decision of 295th meeting of Registration Board	Deferred for following • Evidence of required manufacturing facility / section from Licensing Division. • Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted the following

		• Section approval letter dated 09-03-2015 of M/s English Pharmaceuticals specifying Sterile Dry Powder Injection (Penicillin) section • Differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2536.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Zipbact 4.5g Injection
	Composition	Each Vial Contains: Piperacillin as sodium…4g Tazobactam as sodium…0.5g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4605 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch (Reg# 039439)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/- • Evidence of approval of required manufacturing facility / section could not be confirmed.
	Decision of 295th meeting of Registration Board	Deferred for following • Evidence of required manufacturing facility / section from Licensing Division. • Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.
	Evaluation by PEC[III]	• Firm has submitted the following • Section approval letter dated 09-03-2015 of M/s English Pharmaceuticals specifying Sterile Dry Powder Injection (Penicillin) section • Differential fee PKR 30,000/- dated 12-06-2020.
	Decision: Approved.	
2537.	**Name and address of manufacturer / Applicant**	**M/s Caraway Pharmaceuticals, Plot No. 12, Street # N-3, Rawat Industrial Zone (RCCI), Rawat, Islamabad.** **Contract Manufactured by:** **M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.**
	Brand Name +Dosage Form + Strength	Ompro 40mg Injection
	Composition	Each vial Contains: Omeprazole (as sodium)…..40mg
	Diary No. Date of R& I & fee	Dy.No 1239 dated 12-11-2017 Rs. 50,000/- Dated 12-11-2017

	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & demanded price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40 mg Powder for Solution for Infusion by Sandoz (**MHRA** Approved)
	Me-too status	Risek Injection by Getz
	GMP status	Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017
	Remarks of the Evaluator[3].	• M/s Caraway pharma has 9 approved sections. • Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided **NOT** to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section.
	Decision of 288th meeting of Registration Board	Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement"
	Evaluation by PEC[3]	Registration Board in its 293rd meeting while considering the capacity assessmen report by paenel of inspectors decided as below: Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2538.	**Name and address of manufacturer / Applicant**	**M/s Caraway Pharmaceuticals, Plot No. 12, Street # N-3, Rawat Industrial Zone (RCCI), Rawat, Islamabad.** **Contract Manufactured by:** **M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.**
	Brand Name +Dosage Form + Strength	Vogue 40mg Injection
	Composition	Each vial Contains: Esomeprazole (as sodium)…40mg
	Diary No. Date of R& I & fee	Dy.No 1238 dated 12-11-2017 Rs. 50,000/- Dated 12-11-2017
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & demanded price	1's: As per SRO

	Approval status of product in Reference Regulatory Authorities.	Nexium I.V. 40 mg Powder for solution for injection/infusion by Astrazaneca (**MHRA** Approved)
	Me-too status	Nexum Injection by Getz
	GMP status	Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017
	Remarks of the Evaluator[3].	• M/s Caraway pharma has 9 approved sections. • Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided **NOT** to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section.
	Decision of 288th meeting of Registration Board	Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement"
	Evaluation by PEC[3]	Registration Board in its 293rd meeting while considering the capacity assessmen report by paenel of inspectors decided as below: Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision: Deferred for confirmation of method of manufacturing (lyophilization or dry powder filling) from initially submitted application/dossier.	
2539.	**Name and address of manufacturer / Applicant**	**M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.**
	Brand Name +Dosage Form + Strength	Oromic 2% Gel
	Composition	Each gram contains: Miconazole nitrate……20mg
	Diary No. Date of R& I & fee	Dy No. 13044: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DAKTARINT Oral Gel (MHRA Approved)
	Me-too status	Mecroz 2% Oral Gel by Tabros
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	• The formulation is a mucoadhesive oral gel in BP • The reference formulation contains miconazole 20mg while the applied formulation contains miconazole nitrate 20mg.

	Decision of 291st meeting of Registration Board	Deferred for correction of salt form and revision of formulation along with submission of fee for correction of salt form since the reference product contains miconazole base.
	Evaluation by PEC[3]	Firm has submitted revised master formulation containing miconazole base along with revised Form 5 and method of manufacturing. Firm has also submitted 5,000 fee dated 25-08-2020 for revision of formulation.
	Decision: Approved with following label claim: **Each gram contains:** **Miconazole……20mg**	
2540.	**Name and address of manufacturer / Applicant**	M/s Hiranis Pharmaceuticals, Plot No., E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi,
	Brand Name +Dosage Form + Strength	Infexo DS 250mg Dry Suspension 250mg/5ml
	Composition	Each 5ml of Reconstituted Suspension Contains: Ciprofloxacin …250mg
	Diary No. Date of R& I & fee	DyNo.30785; 12-09-2018; Rs. 20,000/-(fee challan is duplicate)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Cinoxin 250mg Dry Suspension of M/s Searle IV Solutions (Pvt.) Ltd.
	GMP status	Dated: 29-01-2019 The firm is overall GMP compliant.
	Previous Remarks of the Evaluator	COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions is required
	Previous decision (295):	Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions is required.
	Evaluation by PEC[3]	• Firm has submitted relevant documents for source of pellets form M/s Vision pharmaceuticals Islamabad.
	Decision: Approved.	

Case no. 02 Registration applications for registration of oral substitution therapy (OST)

Request of M/s Searle IV Solution for fast track registration of oral substitution therapy (ost)

M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore has applied for registration of following five drugs drugs on Form 5-F (CTD) dated 09-12-2019, as detailed below:

S.No	Name of Product
1	**Senorphine 4mg Tablet** Each sublingual tablet contains Buprenorphine HCl……4mg

2	**Senorphine 8mg Tablet** Each sublingual tablet contains Buprenorphine HCl……8mg
3	**Senorphine 12mg Tablet** Each sublingual tablet contains Buprenorphine HCl……12mg
4	**Seldone 10mg Tablet** Each sublingual tablet contains Methadone HCl……10mg
5	**Seldone 40mg Tablet** Each sublingual tablet contains Methadone HCl……40mg

2. The cases were evaluated and shortcomings were communicated to the applicant on 12th March 2020. It is pertinent to mention that the formulations applied by the firm were different from those approved by reference regulatory authorities which were adopted by Registration Board in its 275th meeting.

3. DRAP Authority in its 84th meeting held on 1st June 2020, considered the request of M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore and advised PE&R Division to once again ask the firm to standardize their applied formulations / dosage form in the light of approvals by reference regulatory authorities and intimate the same to authority for decision on request of M/s Searle IV Solutions (Pvt) Ltd for waiver of the conditions of registration application on Form 5F for OST drugs as a special case with conditions to submit stability data before launching the products.

4. In compliance to the directions of Authority, the firm M/s Searle IV Solutions (Pvt) Ltd was once again issued a letter dated 26th June, 2020 to revise and standardize their applied formulations in line with formulations approved by reference regulatory authorities. In response, the firm has submitted a letter dated 6th July 2020 in which the firm has revised their 4 formulations as per the reference products along with submission of requisite fee.

The details of the revision formulations submitted by the firm are provided in the table below;

Sr. No.	Initially applied Product	Revised Product	Details revision	Evaluation by PEC
1	Senorphine 4mg Tablet Each sublingual tablet contains: Buprenorphine HCl...4mg	Senorphine 4mg Tablet Each sublingual tablet contains: Buprenorphine as HCl ……...4mg	Firm has submitted revised master formulation and label claim alongwith submission of 5,000/- fee for correction of salt form of the API.	The formulation has been revised as per the reference product and the requisite fee (for correction of salt form) is also submitted.
2	Senorphine 8mg Tablet Each sublingual tablet contains: Buprenorphine HCl….8mg	Senorphine 8mg Tablet Each sublingual tablet contains: Buprenorphine as HCl ……8mg	Firm has submitted revised master formulation and label claim alongwith submission of 5,000/- fee for correction of salt form of the API.	The formulation has been revised as per the reference product and the requisite fee (for correction of salt form) is also submitted.
3	Senorphine 12mg Tablet Each sublingual tablet contains: Buprenorphine HCl…12mg	Senorphine 12mg Tablet Each sublingual tablet contains: Buprenorphine as HCl ……12mg	Firm has submitted revised master formulation and label claim alongwith submission of 5,000/- fee for correction of salt form of the API.	The formulation has been revised and the requisite fee (for correction of salt form) is also submitted.
4	Seldone 10mg Tablet Each sublingual tablet contains:	Seldone 10mg Tablet Each tablet contains: Methadone HCl..10mg	Firm has submitted that they have initially applied for plain tablet	The formulation has been revised as per the reference product and

	Methadone HCl…….10mg		and that the word "sublingual tablet" was typographical mistake. Firm has submitted revised master formulation and label claim alongwith submission of 5,000/- fee.	the requisite fee (for correction of salt form) is also submitted.
5	Seldone 40mg Tablet Each sublingual tablet contains: Methadone HCl…….40mg	Seldone 40mg Tablet Each tablet contains: Methadone HCl...40mg	Firm has submitted that they have initially applied for plain tablet and that the word "sublingual tablet" was typographical mistake. Firm has submitted revised master formulation and label claim alongwith submission of 5,000/- fee.	The formulation has been revised as per the reference product and the requisite fee (for correction of salt form) is also submitted.

5. It is pertinent to mention that, the formulation at Sr. No. 03 in the table above is not approved by any reference regulatory authority. In response to this query, the firm has submitted the following documents / Justification:

i. **Proposal for the inclusion of buprenorphine in the WHO Model List of essential medicines dated October 2004.** However, the submitted document does not contain any evidence for 12mg strength of an individual buprenorphine tablet. Firm has referred to the references and recommendations for the overall dose of buprenorphine which varies from 4mg to 12 mg.

ii. **Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence issued by WHO in 2009.** However, the submitted document does not contain any evidence for 12mg strength of an individual buprenorphine tablet.

6. The case was forwarded to DRAP Authority, and the Authority in its 88th meeting considered the case and decided as "***The Authority, exercising it power under Rule 26 of the Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration application on Form 5/ Form 5-A/Form 5-D instead of Form 5-F, for registration of OST i.e. Methadone and Buprenorphine tablets to M/s Searle IV Solutions (Pvt.) Ltd.as a special case because of recommendation by OST project of WHO, in light of approvals granted by the reference regulatory authorities and with the following additional conditions:***

a. The applicants can submit their applications till 15-09-2020 and these applications will be considered out of queue.

b. Registration Board may consider grant of registration to M/s Searle IV Solutions (Pvt.) Ltd. Lahore and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required."

Later, the firm has submitted applications on Form 5D for four of the previously applied products. The evaluation of applications on Form 5D is provided below:

Contract Manufacturing Agreement between Searle IV solutions (Pvt) Ltd and National AIDS Control Program, Islamabad dated 22-10-2019 have been submitted. According to the contents to contract manufacturing agreement, WHO-Pakistan and National AIDS control Program (NACP) has collaborated to introduce oral substitution therapy (OST) in order to curb and eliminate AIDS. This is the medical procedure of replacing an illegal opioid drug such as heroin with longer acting but less euphoric opioid, usually methadone or buprenorphine. WHO-Pakistan has pivotal role and efforts in technical support for roll out of OST in Pakistan. Searle has been selected through EOI to manufacture products for NACP.

2518.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore**
	Brand Name +Dosage Form + Strength	Senorphine 4mg Tablet
	Composition	Each sublingual tablet contains Buprenorphine as HCl……4mg
	Diary No. Date of R& I & fee	**Form 5-F (CTD)** Dy. No. 26455: 09-12-2019 **Form 5D** Dy No. 20054: 17-08-2020 PKR 50,000/-: 09-12-2019
	Pharmacological Group	Opioid receptor partial agonist
	Type of Form	Form 5D
	Finished product Specification	BP
	Pack size & Demanded Price	28's, 10 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	BUPRENORPHINE Mylan 4 mg sublingual tablet (60714918) **ANSM** France Approved.
	Me-too status	Not applicable
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted dated 15-03-2019.
	Remarks of the Evaluator[3]	• Firm has revised the salt form and submitted Fee PKR 5,000 for revision of salt form. • Firm has not submitted stability study data of 3 batches as per the requirements of 251st, 278th, and 293rd meeting of Registration Board.
	Decision: Keeping in view the decision of 88th meeting of DRAP Authority, Registration Board decided to approve the case with the condition that the manufacturer will submit product development data and 6 months accelerated and real time stability studies data before sale of the product.	
2519.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore**
	Brand Name +Dosage Form + Strength	Senorphine 8mg Tablet
	Composition	Each sublingual tablet contains Buprenorphine as HCl……8mg
	Diary No. Date of R& I & fee	**Form 5-F (CTD)** Dy. No. 26456: 09-12-2019 **Form 5D** Dy No. 20055: 17-08-2020 PKR 50,000/-: 09-12-2019
	Pharmacological Group	Opioid receptor partial agonist
	Type of Form	Form 5D
	Finished product Specification	BP
	Pack size & Demanded Price	28's, 10 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	BUPRADEX 8 mg sublingual tablet (64231468) **ANSM** France Approved.
	Me-too status	Not applicable
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted dated 15-03-2019.
	Remarks of the Evaluator[3]	• Firm has revised the salt form and submitted Fee PKR 5,000 for revision of salt form. • Firm has not submitted stability study data of 3 batches as per the requirements of 251st, 278th, and 293rd meeting of Registration Board.
	Decision: Keeping in view the decision of 88th meeting of DRAP Authority, Registration Board decided to approve the case with the condition that the manufacturer will submit product	

	development data and 6 months accelerated and real time stability studies data before sale of the product.	
2520.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore**
	Brand Name +Dosage Form + Strength	Seldone 10mg Tablet
	Composition	Each tablet contains Methadone HCl……10mg
	Diary No. Date of R& I & fee	**Form 5-F (CTD)** Dy. No. 26453: 09-12-2019 **Form 5D** Dy No. 20052: 17-08-2020 PKR 50,000/-: 09-12-2019
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5D
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	25's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metadon Abcur - 10 mg tablet **Norway** Approved.
	Me-too status	Not applicable
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted dated 15-03-2019.
	Remarks of the Evaluator[3]	• Firm has revised the formulation from sublingual tablet to plain tablet and submitted Fee PKR 50,000 for revision of salt form. • Firm has claimed manufacturer's specification while the official monograph for the applied product exist in USP as well as BP. • Firm has not submitted stability study data of 3 batches as per the requirements of 251st, 278th, and 293rd meeting of Registration Board.
	Decision: Keeping in view the decision of 88th meeting of DRAP Authority, Registration Board decided to approve the case with USP specifications and with the condition that the manufacturer will submit product development data and accelerated and 6 months real time stability studies data before sale of the product.	
2521.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, Lahore**
	Brand Name +Dosage Form + Strength	Seldone 40mg Tablet
	Composition	Each tablet contains Methadone HCl……40mg
	Diary No. Date of R& I & fee	**Form 5-F (CTD)** Dy. No. 26454: 09-12-2019 **Form 5D** Dy No. 20053: 17-08-2020 PKR 50,000/-: 09-12-2019
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5D
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	25's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metadon Abcur - 10 mg tablet **Norway** Approved.
	Me-too status	Not applicable
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted dated 15-03-2019.

	Remarks of the Evaluator[3]	• Firm has revised the formulation from sublingual tablet to plain tablet and submitted Fee PKR 50,000 for revision of salt form. • Firm has claimed manufacturer's specification while the official monograph for the applied product exist in USP as well as BP. • Firm has not submitted stability study data of 3 batches as per the requirements of 251st, 278th, and 293rd meeting of Registration Board.
	Decision: Keeping in view the decision of 88th meeting of DRAP Authority, Registration Board decided to approve the case with USP specifications and with the condition that the manufacturer will submit product development data and accelerated and 6 months real time stability studies data before sale of the product.	

Firm has not submitted any response against the following case.

2522.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, District Lahore.**
	Name, address of Manufacturing site.	M/s Searle IV Solutions (Pvt) Ltd., 1.5Km Manga Raiwind Road Manga Mandi, District Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted dated 15-03-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 11-04-2016 for Tablet (Psychotropic) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26457: 09-12-2019
	Details of fee submitted	PKR 50,000/-: 09-12-2019
	The proposed proprietary name / brand name	**Senorphine 12mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sublingual tablet contains Buprenorphine HCl……12mg
	Pharmaceutical form of applied drug	White to off white coloured oblong tablets with Searle engraved on one side and bisect line on other side.
	Pharmacotherapeutic Group of (API)	Opioid receptor partial agonist
	Reference to Finished product specifications	BP
	Proposed Pack size	28's, 10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Could not be confirmed**
	For generic drugs (me-too status)	Not applicable

	Name and address of API manufacturer.	**Not submitted**
	Module-II (Quality Overall Summary)	**Not submitted**
	Module-III Drug Substance:	**Not submitted**
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Not submitted**
	Module-III Drug Product:	**Not submitted**
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Not submitted**
	Analytical method validation/verification of product	**Not submitted**

STABILITY STUDY DATA

Manufacturer of API	Micro Orgo-Chem, Shed No. C1 B 57, LIC Sector GIDC Vapi Dist. Valsad India.		
API Lot No.	**Not submitted**		
Description of Pack (Container closure system)	**Not submitted**		
Stability Storage Condition	**Not submitted**		
Time Period	**Not submitted**		
Frequency	**Not submitted**		
Batch No.	**Not submitted**	**Not submitted**	**Not submitted**
Batch Size	**Not submitted**	**Not submitted**	**Not submitted**
Manufacturing Date	**Not submitted**	**Not submitted**	**Not submitted**
Date of Initiation	**Not submitted**	**Not submitted**	**Not submitted**
No. of Batches	**Not submitted**		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	**Not submitted**
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. S-GMP/1991608) issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 23-09-2021.
3.	Protocols followed for conduction of stability study and details of tests.	**Not submitted**
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	**Not submitted**
5.	Documents confirming import of API etc.	**Not submitted**
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	**Not submitted**

7.	Commitment to continue real time stability study till assigned shelf life of the product.	**Not submitted**
8.	Commitment to follow Drug Specification Rules, 1978.	**Not submitted**

REMARKS OF EVALUATOR[3]

Contract Manufacturing Agreement between Searle IV solutions (Pvt) Ltd and National AIDS Control Program, Islamabad dated 22-10-2019 have been submitted. According to the contents to contract manufacturing agreement, WHO-Pakistan and National AIDS control Program (NACP) has collaborated to introduce oral substitution therapy (OST) in order to curb and eliminate AIDS. This is the medical procedure of replacing an illegal opioid drug such as heroin with longer acting but less euphoric opioid, usually methadone or buprenorphine. WHO-Pakistan has pivotal role and efforts in technical support for roll out of OST in Pakistan. Searle has been selected through EOI to manufacture products for NACP.

Following shortcomings were communicated to the firm, but the firm has not submitted any response against the letter of shortcoming.

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.
- Clarify whether the application is for new or generic drug product, since you have selected Generic drug product in section 1.4.1, while mentioned "Not applicable" against section 1.5.8 where reference of other similar medicine approved by DRAP is required.
- Quality Overall Summary (QOS) needs to be submitted as per WHO QOS-PD template.
- Data of drug substance as per the requirements of Module 3 section 3.2.S needs to be submitted.
- Justify the formulation development through comparative analysis by testing your product against the reference / innovator product as well as by performing comparative dissolution profile against the reference / innovator product.
- Submit details of manufacturing process development as per the requirement of section 3.2.P.2.3.
- Process controls and critical process parameters needs to identified and submitted as per the requirement of section 3.2.P.3.3.
- Control of critical steps and intermediates needs to be submitted as per the requirements of section 3.2.P.3.4.
- Data of verification of analytical method needs to be submitted as per the requirements of 3.2.P.5.3.
- Batch analysis needs to be submitted as per the requirements of 3.2.P.5.4.
- Information pertaining to reference standard or materials needs to be submitted as per the requirements of 3.2.P.6.
- Stability study data of 3 batches along with associated documents as described in 293rd meeting of Registration Board needs to be submitted as per the requirements of section 3.2.P.8.

Decision: Registration Board decided to defer the case for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.**
- **Complete data of Form 5F (CTD) as per the guidance document approved by Registration Board in the instant meeting.**

Case no. 03 Registration applications of CTD cases

a. New cases of Import

2523.	**Name, address of Applicant / Importer**	**M/s Medi Mark Pharmaceuticals, 588-B/1, Liaquat Chowk, Sahiwal.**
	Details of Drug Sale License of importer	**License No:** 02-367-0154-049333D **Address:** Karbala Road House No. 588, Sahiwal **Validity:** 20-12-2021 **Status:** License to sell drugs as distributor

	Name and address of marketing authorization holder (abroad)	Imax Diagnostic Imaging Limited Phoneix House, Room 137, Monhan Road T12 H1XY ork Ireland.
	Name, address of manufacturer(s)	**Details as per CoPP** **Immediate packaging**: Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Bulk Manufacturer** Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Outer packaging** Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria. Fresenius Kabi Austria GmbH (Fab. Werndorf II) Am Gewerbepark 6, 8402 Austria. Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Details as per Module 2 / Module 3** **Address of site of manufacturer** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Primary Packaging** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Labelling and secondary Packaging** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. And/or Fresenius Kabi Austria GmbH Am Gewerbepark 6, A-8402 Wendorf Austria. And/or Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria. **In process testing** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **QC Testing** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Visual and optical control** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria.
	Name of exporting country	Portugal
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 1596/CM/2019) dated 23-09-2019 issued by Autoridade Nacional do Medicamento e Produtos de Saude I.P (INFARMED) Parque de Saude de Lisboa, Av. Do Brasil N. 53 1749-004 Lisboa Portugal (translated to English from google translate "National authority for medicines and health products I.P (INFARMED) Lisbon Health Park, Av. Do Brasil

		N. 53 1749-004 Lisboa Portugal") for Iohexol imax 647mg/ml solution for injection.. The CoPP confirms free sale status of the product in exporting country but the GMP status of the manufacturing facility is not confirmed. As per the contents of CoPP the applicant for the certificate was PharSolution – Pharmaceutical Consulting, Lda. Av. Bombeiros Voluntarios, nº 146- 1º 2765-201 Estoril Portugal. Firm has submitted that the product is approved in following three European countries which are part of EC and are also considered as reference for the criteria of reference regulatory authorities. **1. Estonia:** Iohexol Imax 647mg / 1ml of IMAX Diagnostic Imaging Limited. The product is confirmed from the official website of Agency of Medicines Republic of Estonia through the following link https://www.ravimiregister.ee/en/default.aspx?pv=Loendid.Pakend&vid=1d9ac7f7-0bc5-470c-9368-a14ee7962835 (Accessed on 12-08-2020) **2. Lithuania:** Iohexol Imax 647mg / 1ml of IMAX Diagnostic Imaging Limited Ireland. The product is confirmed from the official website of Community Register of Medicinal Products State Drug Control Service Republic of Lithuania through the following link https://vapris.vvkt.lt/vvkt-web/public/medications (Accessed on 12-08-2020) **3. Latvia:** Iohexol Imax 647mg / 1ml of IMAX Diagnostic Imaging Limited Ireland. The product is confirmed from the official website of Latvian Register of Medicines, Latvia through the following link https://www.zva.gov.lv/zvais/zalu-registrs/info/15-0176?r=L3p2YWlzL3phbHUtcmVnaXN0cnMvP2lzcz0xJmFtcDtxPUlvaGV4b2wrSW1heCZhbXA7SUstMT0xJmFtcDtJSy0yPTI= (Accessed on 12-08-2020) **GMP**: **Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria.** Firm has submitted copy of GMP certificate (No. 480166-0097) issued by Austrian Medicine and Medical Devices Agency dated 10-05-2019 based on the inspection report dated 08-02-2018 The certificate is verifiable from Eudra GMP database. **Fresenius Kabi Austria GmbH** **Am Gewerbepark 6, A-8402 Wendorf Austria** Firm has submitted copy of GMP certificate (No. 482159-0040) issued by Austrian Medicine and Medical Devices Agency dated 28-08-2018 based on the inspection report dated 24-05-2018 The certificate is verifiable from Eudra GMP database. **Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria.** Firm has submitted copy of GMP certificate (No. 480019-0063) issued by Austrian Medicine and Medical Devices Agency dated 10-12-2018 based on the inspection report dated

		28-09-2018 The certificate is verifiable from Eudra GMP database.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Imax Diagnostic Imaging Limited Phoenix house, Room 137, Monhan Road, T12 H1XY Cork, Ireland. The letter species that Imax diagnostic are the license holder of Iohexol 647mg/ml and Iohexol 755mg/ml and that they authorize Medi Mark Pharmaceuticals as their local agents to be responsible for all regulatory affairs of these products in Pakistan. The authorization letter was issued on 18 December 2019 and is valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 8448: 21-04-2020
	Details of fee submitted	PKR 100,000/-: 04-03-2020
	The proposed proprietary name / brand name	**IOHEXOL iMAX 647mg/ml solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 647mg Iohexol equivalent to organic iodine……300mg
	Pharmaceutical form of applied drug	Clear and colorless to slightly yellowish solution filled in 100ml glass vials
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, low osmolar X-ray contrast media (**V08AB02)**
	Reference to Finished product specifications	USP
	Proposed Pack size	10 vials of 100ml
	Proposed unit price	Rs. 6000/- of 50ml Rs. 10,000 of 100ml
	The status in reference regulatory authorities	Omnipaque - 300 mg I/ ml **(Norway** Approved)
	For generic drugs (me-too status)	Omnipaque Injection by Apex Pvt Ltd (Reg #008867)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Materials Base, Linhai Park Zhejiang Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also referred to their CEP certificate (No. R1-CEP 2009-192-Rev 02) which is also verified from EDQM CEP certification online database.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC / 60% RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted comparative table summarizing results of all physico-chemical tests performed on 5 batches of applied product and one batch of the reference product i.e. Omnipaque injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Iohexol solution for injection will be filled into Type I glass vials. The vials are closed with chlorobutyl rubber stoppers and capped with aluminium / plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at following conditions: • 40ºC ±2ºC / <25% RH for 6 months • 25ºC ±2ºC / 60% ± 5% RH for 36 months (testing only at initial and last time point) • 30ºC ±2ºC / 65% ± 5% RH for 36 months
Evaluation by PEC[3]:		
Decision: Approved as per Policy for inspection of Manufacturer abroad.		
2524.	**Name, address of Applicant / Importer**	**M/s Medi Mark Pharmaceuticals, 588-B/1, Liaquat Chowk, Sahiwal.**
	Details of Drug Sale License of importer	**License No:** 02-367-0154-049333D **Address:** Karbala Road House No. 588, Sahiwal

		Validity: 20-12-2021 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	Imax Diagnostic Imaging Limited Phoneix House, Room 137, Monhan Road T12 H1XY ork Ireland.
	Name, address of manufacturer(s)	**Details as per CoPP** **Immediate packaging**: Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Bulk Manufacturer** Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Outer packaging** Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria. Fresenius Kabi Austria GmbH (Fab. Werndorf II) Am Gewerbepark 6, 8402 Austria. Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria. **Details as per Module 2 / Module 3** **Address of site of manufacturer** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Primary Packaging** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Labelling and secondary Packaging** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. And/or Fresenius Kabi Austria GmbH Am Gewerbepark 6, A-8402 Wendorf Austria. And/or Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria. **In process testing** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **QC Testing** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria. **Visual and optical control** Fresenius Kabi Austria GmbH Hafnerstrasse, 36 A-8055 Graz Austria.
	Name of exporting country	Portugal

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 1595/CM/2019) dated 23-09-2019 issued by Autoridade Nacional do Medicamento e Produtos de Saude I.P (INFARMED) Parque de Saude de Lisboa, Av. Do Brasil N. 53 1749-004 Lisboa Portugal (translated to English from google translate "National authority for medicines and health products I.P (INFARMED) Lisbon Health Park, Av. Do Brasil N. 53 1749-004 Lisboa Portugal") for Iohexol imax 647mg/ml solution for injection.. The CoPP confirms free sale status of the product in exporting country but the GMP status of the manufacturing facility is not confirmed. As per the contents of CoPP the applicant for the certificate was PharSolution – Pharmaceutical Consulting, Lda. Av. Bombeiros Voluntarios, nº 146-1º 2765-201 Estoril Portugal. **GMP**: **Fresenius Kabi Austria GmbH (Fab. Graz) Hafnerstrasse, 36 A-8055 Graz Austria.** Firm has submitted copy of GMP certificate (No. 480166-0097) issued by Austrian Medicine and Medical Devices Agency dated 10-05-2019 based on the inspection report dated 08-02-2018 The certificate is verifiable from Eudra GMP database. **Fresenius Kabi Austria GmbH** **Am Gewerbepark 6, A-8402 Wendorf Austria** Firm has submitted copy of GMP certificate (No. 482159-0040) issued by Austrian Medicine and Medical Devices Agency dated 28-08-2018 based on the inspection report dated 24-05-2018 The certificate is verifiable from Eudra GMP database. **Fresenius Kabi Austria GmbH (Fab. Linz) Estermannstrasse, 17 A-4020 Linz Austria.** Firm has submitted copy of GMP certificate (No. 480019-0063) issued by Austrian Medicine and Medical Devices Agency dated 10-12-2018 based on the inspection report dated 28-09-2018 The certificate is verifiable from Eudra GMP database.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Imax Diagnostic Imaging Limited Phoenix house, Room 137, Monhan Road, T12 H1XY Cork, Ireland. The letter species that Imax diagnostic are the license holder of Iohexol 647mg/ml and Iohexol 755mg/ml and that they authorize Medi Mark Pharmaceuticals as their local agents to be responsible for all regulatory affairs of these products in Pakistan. The authorization letter was issued on 18 December 2019 and is valid for 5 years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 8447: 21-04-2020
	Details of fee submitted	PKR 100,000/-: 04-03-2020
	The proposed proprietary name / brand name	**IOHEXOL iMAX 755mg/ml solution for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 755mg Iohexol equivalent to organic iodine……350mg
	Pharmaceutical form of applied drug	Clear and colorless to slightly yellowish solution filled in 100ml glass vials
	Pharmacotherapeutic Group of (API)	Watersoluble, nephrotropic, low osmolar X-ray contrast media (**V08AB02)**
	Reference to Finished product specifications	USP
	Proposed Pack size	10 vials of 100ml
	Proposed unit price	Rs. 12,000 of 100ml
	The status in reference regulatory authorities	Omnipaque - 350 mg I/ ml **(Norway** Approved)
	For generic drugs (me-too status)	Omnipague Injection by Apex Pvt Ltd (Reg #008868)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Materials Base, Linhai Park Zhejiang Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also referred to their CEP certificate (No. R1-CEP 2009-192-Rev 02) which is also verified from EDQM CEP certification online database.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC / 60%

		RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted complete data of formulation development process. Firm has submitted comparative quantitative composition of applied product along with reference product. Firm has also submitted comparative table summarizing results of all physico-chemical tests performed on 5 batches of applied product and one batch of the reference product i.e. Omnipaque injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Iohexol solution for injection will be filled into Type I glass vials. The vials are closed with chlorobutyl rubber stoppers and capped with aluminium / plastic flip-off seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at following conditions: • 40ºC ±2ºC / <25% RH for 6 months • 25ºC ±2ºC / 60% ± 5% RH for 36 months (testing only at initial and last time point) • 30ºC ±2ºC / 65% ± 5% RH for 36 months
Evaluation by PEC[3]:		
Decision: Approved as per Policy for inspection of Manufacturer abroad.		
2525.	**Name, address of Applicant / Importer**	**M/s Gene Tech Laboratories, B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** DHSKDK(Drug)/-1824 **Address:** 246/B PECHS Block 6, Karachi. **Validity:** 15-08-2020 **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran
	Name, address of manufacturer(s)	Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 665/7637) dated 29-04-2019 issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran for Lenoma 10mg Capsule. The CoPP confirms free sale status of the product in Iran as well as GMP status of the manufacturing site through periodic inspection atleast once in an year. **GMP:** Firm has submitted original, legalized GMP

		certificate (Ref 665/7613) of Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran. The certificate was issued on 29-4-2019 and the **certificate was valid for one year.** **Free Sale Certificate:** Firm has submitted original, legalized Free sale certificate (Ref 665/7640) of Lenoma 10mg Capsule issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran. The certificate was issued on 29-4-2019
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized N.O.C letter from NanoAlvand Co. where the firm authorizes "Gene Tech Laboratories" with registered address at 246/B PECHS Block 6, Karachi to register, import and market Lenoma Capsule. The letter was issued on 16-07-2019.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31773: 28-01-2020
	Details of fee submitted	PKR 100,000/-: 31-12-2019
	The proposed proprietary name / brand name	**LENOMA 10mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide……10mg
	Pharmaceutical form of applied drug	white to off white powder filled in size '2' Hard Gelatin Capsule with white opaque body imprinted 360 degrees' line with red ink and orange opaque cap.
	Pharmacotherapeutic Group of (API)	Antineoplastic and immunomodulating agents/immunosuppresants (**L04AX)**
	Reference to Finished product specifications	In house
	Proposed Pack size	21's
	Proposed unit price	2.22$ / capsule
	The status in reference regulatory authorities	Revlimid Capsule **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Name, address of drug substance manufacturer	Dr. Reddy's Laboratories Limited. D. No. 8-2-337, Road No. 3, Banjara Hills Hyderabad India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for drug substances including stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted at 5ºC ± 3ºC.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted details of formulation development study. Firm has used Revlimid® (Lenalidomide) Capsules manufactured by Celgene Corporation as comparator product. Firm has performed testing of comparator product and used its values for developing their own formulation. Firm has submitted results of all tests as well comparative dissolution profile.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for the applied product.
	Container closure system of the drug product	Alu-Alu blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches LNL.10.96.01, LNL.10.96.02 and LNL.10.96.03. The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 24 months.
Evaluation by PEC[3]:		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		
2526.	**Name, address of Applicant / Importer**	**M/s Gene Tech Laboratories, B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** DHSKDK(Drug)/-1824 **Address:** 246/B PECHS Block 6, Karachi. **Validity:** 15-08-2020 **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran

	Name, address of manufacturer(s)	Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 665/7642) dated 29-04-2019 issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran for Lenoma 25mg Capsule. The CoPP confirms free sale status of the product in Iran as well as GMP status of the manufacturing site through periodic inspection atleast once in an year. **GMP:** Firm has submitted original, legalized GMP certificate (Ref 665/7613) of Nano Fanavaran Darouei Alvand (NanoAlvand) W7 St., Simin Dasht Industrial Area, Karaj, Alborz, Iran issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran. The certificate was issued on 29-4-2019 and the **certificate was valid for one year.** **Free Sale Certificate:** Firm has submitted original, legalized Free sale certificate (Ref 665/7857) of Lenoma 25mg Capsule issued by Food and drug administration, Ministry of Health and medical education, Islamic Republic of Iran. The certificate was issued on 29-4-2019
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized N.O.C letter from NanoAlvand Co. where the firm authorizes "Gene Tech Laboratories" with registered address at 246/B PECHS Block 6, Karachi to register, import and market Lenoma Capsule. The letter was issued on 16-07-2019.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31772: 28-01-2020
	Details of fee submitted	PKR 100,000/-: 31-12-2019
	The proposed proprietary name / brand name	**LENOMA 25mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide……25mg
	Pharmaceutical form of applied drug	white to off white powder filled in size '0' Hard Gelatin Capsule with brown opaque cap.
	Pharmacotherapeutic Group of (API)	Antineoplastic and immunomodulating agents/immunosuppresants (**L04AX)**
	Reference to Finished product specifications	In house
	Proposed Pack size	21's
	Proposed unit price	4.62$ / capsule

	The status in reference regulatory authorities	Revlimid Capsule **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Dr. Reddy's Laboratories Limited. D. No. 8-2-337, Road No. 3, Banjara Hills Hyderabad India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for drug substances including stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted at 5ºC ± 3ºC.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted details of formulation development study. Firm has used Revlimid® (Lenalidomide) Capsules manufactured by Celgene Corporation as comparator product. Firm has performed testing of comparator product and used its values for developing their own formulation. Firm has submitted results of all tests as well comparative dissolution profile.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for the applied product.
	Container closure system of the drug product	Alu-Alu blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches LNL.25.96.02, LNL.25.96.03, and LNL.25.96.04. The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 24 months.
Evaluation by PEC[3]:		

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		
2527.	**Name, address of Applicant / Importer**	**M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0066-037256D **Address:** 65-Industrial estate, Kot Lakhpat District Lahore. **Go-down(s) address:** 15-M, Industrial Estate, Kot Lakhpat, District Lahore **Validity:** 05-10-2020 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	Phil Inter Pharma Co. Ltd. No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam
	Name, address of manufacturer(s)	Phil Inter Pharma Co Ltd., No. 25, street No. 8, VSIP, Thuan An District. Binh Duong. Vietnam.
	Name of exporting country	Vietnam
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 714/GP-QLD) dated 23-09-2019 issued by Drug Administration, Ministry of Health of Vietnam for MAXVAS soft capsule (export name). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **GMP**: Firm has submitted legalized copy of letter for issuance of GMP certificate in Vietnam local language as well as translated copy in English. As per the contents of letter, M/s Phil Inter Pharma Co Ltd., No. 25, street No. 8, Vietnam Singapore Industrial Park (VSIP), Thuan An District. Binh Duong. Vietnam was inspected on 20-21 August 2019 by assessment team of Drug Administration of Vietnam, where the Drug Administration agrees to permit the firm to continue manufacturing and registering drugs. This official letter takes effect for 3 months from the date of signing and replaces or the official letter dated 01-10-2019. The letter is issued by Vice director Department of Drug Registration, Drug Administration of Vietnam on 3rd October 2019.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy letter of authorization from Phil Inter Pharma Co. Ltd. as per the contents of letter, "*Phil Inter Pharma Co. Ltd authorizes CCL Pharmaceuticals(Pvt) Ltd to carry out all drug registration procedures for dutasteride 0.5mg*" The letter of authorization do not bear any date.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27482: 18-12-2019
	Details of fee submitted	PKR 100,000/-: 18-12-2019
	The proposed proprietary name / brand name	**MAXVAS soft capsule 0.5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Dutasteride……0.5mg
	Pharmaceutical form of applied drug	Light yellow oblong soft capsules containing transparent colourless drug substance
	Pharmacotherapeutic Group of (API)	Testosterone-5-alpha reductase inhibitors (**G04CB02)**
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per innovator price
	The status in reference regulatory authorities	Avodart 0.5mg soft capsules **(MHRA** Approved)
	For generic drugs (me-too status)	Avodart capsule by GSK (Reg #041157)
	Module-II (Quality Overall Summary)	**Not submitted**
	Name, address of drug substance manufacturer	MSN Laboratories (Pvt) Ltd. Sy No. 317 & 323, Rudaram (Village), Patanchery (Mandal), Medak District, Telangana India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C / 60% RH. The stability study data is till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Not submitted**
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Aluminium-PVC blister

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH for 36 months.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Justify the application for import along with fee (PKR 100,000/-) submitted on the basis of "Drug Manufacturing License" instead of "Drug Sale License".	The submitted fee (PKR 100,000) is for imported products. DML was submitted w.r.t. facility proof for local repacking and also submitting copy of Drug Sale License (DSL) for import. **The fee receipt contains DML number of the firm.**
You have selected the option "Bulk import and local repackaging" in section 1.4.2 without specifying the status of bulk, and provided multiple pack sizes in section 1.5.4. Furthermore the CoPP is also for the finished product. Clarification is required in this regard.	Please be informed that the product is bulk import and local repacking as mentioned in 1.4.2. Multiple pack sizes were mentioned because after bulk import, product will be packed in pack sizes as mentioned in 1.5.4.
Letter of authorization / sole agency agreement between the applicant firm in Pakistan and marketing authorization holder abroad specifying the applied product needs to be submitted.	Firm has submitted copy letter of authorization from Phil Inter Pharma Co. Ltd. as per the contents of letter, "Phil Inter Pharma Co. Ltd authorizes CCL Pharmaceuticals(Pvt) Ltd to carry out all drug registration procedures for dutasteride 0.5mg" **The letter of authorization do not bear any date.**
Quality overall summary (QOS) in module 2 needs to be submitted as per WHO QOS-PD template or the template approved by Registration Board in its 293rd meeting.	Firm has submitted QOS as per WHO QOS-PD template
Submit data in section 3.2.P.2.2.1 as per the decision of 293rd meeting of Registration Board, which states that "*Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed"*.	Firm has submitted results of pharmaceutical equivalence against the Avodart capsule. **The pharmaceutical equivalence report is signed by technical persons of CCL Pharma, while the document does not contain any endorsement or signatures from the manufacturer abroad.**

Following observations are not yet addressed:

- Firm has submitted application on the basis of their DML. The DML number is mentioned on the fee receipt of the application. Now the firm has also submitted copy of DSL but the fee receipt still contains the DML number as well as addressof DML site.
- The letter of authorization does not contains any date nor the validity.
- The pharmaceutical equivalence report is signed by technical persons of CCL Pharma, while the document does not contain any endorsement or signatures from the manufacturer abroad.
- As per the details of manufacturer of finished product, Phil Inter Pharma Co. Ltd is mentioned as manufacturer of the finished product including the step of packaging.
- The comparative dissolution profile is performed by Phil Inter Pharma Co. Ltd, which is not the batch release site since the final packaging of capsules is to be performed by CCL Pharmaceuticals.
- The complete module 3 and 2 specifies that the product manufactured by Phil Inter Pharma Co. Ltd is packed in Alu-PVC blister packs further packed in unit carton, while the module 1 specifies that the firm is importing bulk capsules.
- The description of container closure for the drug to be imported mentioned in module 3 section 3.2.P.7 is Alu-PVC blister pack, while the firm has applied for import of bulk capsules which they

will blister and finally pack in Pakistan. The details of container closure system which contains bulk capsules should be submitted.

- The stability study of the drug product submitted by Phil Inter Pharma Co. Ltd in module 3 section 3.2..P.8.3 is for capsules packed in Alu-PVC blister packs, while the applied case is different. The stability studies from Phil Inter Pharma Co. Ltd should have been conducted in the container which will contain the bulk capsules. Furthermore the stability studies after blistering and packing should be conducted by CCL Pharmaceuticals.
- Since the firm is importing on the basis of DSL, therefore an agreement for the blistering, packaging and batch release from the DML site should be submitted.
- Since the batch analysis is to be performed by CCL Pharmaceuticals, therefore the finished product specifications, analytical method, validation of analytical methods and batch analysis should be submitted by CCL Pharmaceuticals.

Decision: Deferred for following submissions:

- **Clarification regarding the application whether submitted on the basis of Drug Manufacturing License (DML) or Drug Sale License (DSL).**
- **Clarification regarding the submitted letter of authorization since it does not contain any issuance or validity date.**
- **Clarification, how the pharmaceutical equivalence report is signed by the technical person of CCL Pharmaceuticals while the study was conducted by manufacturer abroad i.e. Phil Inter Pharma Co Ltd., Vietnam.**
- **Clarification of application of bulk import local repacking, since the submitted Form 5F specifies that the blistering and final packing steps are also performed by the manufacturer abroad i.e. Phil Inter Pharma Co Ltd., Vietnam.**
- **Submission of complete data of module 2 as well as module 3 to justify the requirements of bulk import and local repacking.**

2528.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	Aqvida, GmbH Kaiser-Wilhelm-Straβe 89 20355 Hamburg Germany.
	Name, address of manufacturer(s)	AqVida GmbH Werkstr.21 23942 Dassow Germany.
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. AQV/130219/6) dated 13-02-2019 issued by Behorde fur Gesundheit und Verbraucherschutz der Freien und Hansestadt Hamburg Abteilung V4 Pharmaziewesen und Medizinprodukte Billstraβe 80 20539 Hamburg Germany Google translation "*Authority for Health and consumer protection of the free and hanseatic city of Hamburg. Department of Pharmaceuticals and Medical devices Billstraβe 80 20539 Hamburg Germany*" for Paclitaxel AqVida 6mg/ml concentrate for solution for infusion (150mg/25ml). The CoPP confirms free sale status of the product in Germany as well as GMP status of the manufacturing site through periodic inspection in every 2 years.
	Details of letter of authorization / sole agency agreement	Firm has submitted a **copy** of letter of authorization from AQVIDA Aqvida GmbH Kaiser Wilhelm-str 89-20355 Hamburg. According to the letter, the firm AQVIDA Aqvida GmbH authorizes "Himmel

		Pharma" with registered address at 793-D Block C Faisal Town Lahore to register and market Paclitaxel AqVida. The letter was issued on 13-03-2020.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1194: 19-03-2019
	Details of fee submitted	PKR 100,000/-: 19-03-2019
	The proposed proprietary name / brand name	**Paclitaxel AqVida 150mg/25ml concentrate for solution for infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Paclitaxel……6mg
	Pharmaceutical form of applied drug	Sterile, clear yellowish viscous solution
	Pharmacotherapeutic Group of (API)	Taxane, Anticancer: (**L01CD01)**
	Reference to Finished product specifications	Eu. Phr
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paclitaxel 6 mg/ml Concentrate for Solution for Infusion **(MHRA** Approved)
	For generic drugs (me-too status)	Anzatax Injection by Atco (Reg # 021091)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Phyton Biotech LLC 1503 Cliveden Avenue Delta B.C Canada. V3M6P7
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated and real time conditions. The real time stability data is conducted as per 30°C ±2°C / 65% ± 5% RH for 12 months and as per 25°C

		±2°C / 60% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation repport, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted details of formulation development study. Firm has used Taxol Injection 6mg/ml manufactured by Bristol myers squibb company as comparator product. Firm has performed assay and impurities testing of comparator product and their own product. The results were comparable
	Analytical method validation/verification of product	Firm has submitted method transfer studies for the drug product
	Container closure system of the drug product	Type I colorless glass vial which is closed with PTEF coated butyl rubber stopper and is sealed with aluminium cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches AS1801, AS1802 and AS1803. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH for 36 months.

Evaluation by PEC[3]:

The official monograph exists in USP however firm has not selected USP specification instead they have developed specifications baed on European pharmacopeia. The comparison of specs of the USP and those selected by the firm are tabulated below:

Tests	**USP Specs**	**Firm's specs**
Assay	90 – 110 (HPLC)	95 – 105 (HPLC)
pH	3 – 7	3 – 4.9
Limit of degradation products	**Name** / **Limit (%)** Baccatin III – 0.8 Ethyl ester side chain – 0.4 10-Deacetylpaclitaxel – 0.8 10-Deacetyl-7-epipaclitaxel (Paclitaxel related compound B – 0.5 7-Epipaclitaxel – 0.6	**Name** / **Limit (%)** Baccatin III – 0.2 N-Benzoylphenylisoserine ethylester 10 – 0.2 10-Deacetylpaclitaxel – 0.2 Cephalomannine and isomer (impurity A/B) – 0.7 7-Epipaclitaxel – 0.4 10-Deacetyl-7-epipaclitaxel – 0.4

Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad.

2529.	**Name, address of Applicant / Importer**	**M/s Punjab Medical Service, Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-041061D **Address:** Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore.

		Go-down(s) address: NA **Validity:** 27-02-2021 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	Onko Ilac San ve. Tic. A.S Kosuyolu Cad. No. 34 34718, Kosuyolu Kadikoy / Istanbul Turkey.
	Name, address of manufacturer(s)	Onko Ilac Sanayi ve Ticaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No. 1703 Gebze, Kocaeli, Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2020/1253) dated 11-05-2020 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey for Mextu 50mg/2mL IM/IV/IA/IT solution for injection and infusion. The CoPP confirms free sale status of the product in Turkey as well as GMP status of the manufacturing site through periodic inspection in every 3 years. The certificate is valid till 11-05-2022.
		GMP: Firm has submitted **copy** of certificate of GMP compliance of manufacturer (No. TR/GMP/2017/188) dated 08-11-2017 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The certificate was **valid till May 2019**.
	Details of letter of authorization / sole agency agreement	Firm has submitted a **copy** of letter of authorization from General Director of *Onko Ilac San ve. Tic. A.S* located at Kosuyolu Cad. No. 34 34718, Kadikoy / Istanbul Turkey. According to the letter, the firm Onko Ilac San ve. Tic authorizes "Punjab Medical Services" with registered address at Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore to perform the registration procedures, sales and other similar activities concerning medicinal products for territory of Pakistan. The letter was issued on 22-03-2018 and it is valid for three years from date of issue. The appendix 1 of the letter of authorization contains products list containing Mextu 50mg, 500mg and 1000mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1197: 19-03-2019
	Details of fee submitted	PKR 100,000/-: 19-03-2019

	The proposed proprietary name / brand name	**MEXTU 50mg/2ml IM/IV/IA/IT Solution for Injection and Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Methotrexate……25mg
	Pharmaceutical form of applied drug	Yellowish, clear solution filled in clear glass vial, sealed with rubber closure and aluminium flip off brown seal.
	Pharmacotherapeutic Group of (API)	Cytostatic agent: Folic Acid analogue (**L01BA01)**
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methotrexate 25 mg/ml solution for injection **(MHRA** Approved)
	For generic drugs (me-too status)	Methotrexate injection by Atco (Reg#016151)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Excella GmbH Nurnberger Strasse 12 D-90537 Feucht Germany
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also referred to their CEP certificate No. R1-CEP 2000-024-Rev 10 which is verified from EDQM database.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has also referred to their CEP certificate No. R1-CEP 2000-024-Rev 10 which is verified from EDQM database.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted details of formulation development study. Firm has used Methotrexate Injection 25mg/ml (200mg/8mL) manufactured by Cynamid of Great Britan Ltd England as comparator

		product. Firm has performed testing of comparator product and used its values for developing their own formulation. Firm has provided detailed process of formulation development including results of various experiments to control pH and other parameters.
	Analytical method validation/verification of product	Firm has submitted that the product was initially registered as an import license product and manufactured in Intas Pharmaceuticals India in 2014. After that they file a variation application for replacement of manufacturing site to Onko Ilac Turkey in 2015. During this variation application manufacturing method transfer and analytical method transfer studies were performed. Process validation, batch analysis and stability studies were also performed. The application was approved from MoH in 2016.
	Container closure system of the drug product	10mL Type-I clear glass vial (6R transparent glass vial) with 20mm Chlorobuthyl grey rubber stopper and 20mm Aluminium flip-off brown seal
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 50500400, 5060700 and 50700900. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH for 24 months.
Evaluation by PEC[3]:		
Decision: Approved as per Policy for inspection of Manufacturer abroad.		
2530.	**Name, address of Applicant / Importer**	**M/s Punjab Medical Service, Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-041061D **Address:** Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore. **Go-down(s) address:** NA **Validity:** 27-02-2021 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	Onko Ilac San ve. Tic. A.S Kosuyolu Cad. No. 34 34718, Kosuyolu Kadikoy / Istanbul Turkey.
	Name, address of manufacturer(s)	Onko Ilac Sanayi ve Ticaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No. 1703 Gebze, Kocaeli, Turkey
	Name of exporting country	Turkey

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. 2020/1254) dated 11-05-2022 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey for Mextu 500mg/20mL IM/IV/IA/IT solution for injection and infusion. The CoPP confirms free sale status of the product in Turkey as well as GMP status of the manufacturing site through periodic inspection in every 3 years. The certificate is valid till 11-05-2022.
		GMP: Firm has submitted **copy** of certificate of GMP compliance of manufacturer (No. TR/GMP/2017/188) dated 08-11-2017 issued by Turkish Medicines and Medical Devices Agency, Ministry of Health, Republic of Turkey. The certificate was **valid till May 2019**.
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of letter of authorization from General Director of *Onko Ilac San ve. Tic. A.S* located at Kosuyolu Cad. No. 34 34718, Kadikoy / Istanbul Turkey. According to the letter, the firm Onko Ilac San ve. Tic authorizes "Punjab Medical Services" with registered address at Office No. 4/5 2nd Floor Jalal Center opposite OPD Gate Sir Gangaram Hospital Mozang Road Lahore to perform the registration procedures, sales and other similar activities concerning medicinal products for territory of Pakistan. The letter was issued on 22-03-2018 and it is valid for three years from date of issue. The appendix 1 of the letter of authorization contains products list containing Mextu 50mg, 500mg and 1000mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1196: 19-03-2019
	Details of fee submitted	PKR 100,000/-: 19-03-2019
	The proposed proprietary name / brand name	**MEXTU 500mg/20ml IM/IV/IA/IT Solution for Injection and Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Methotrexate……25mg
	Pharmaceutical form of applied drug	Yellow, clear solution filled in clear glass vial, sealed with rubber closure and aluminium flip off seal.
	Pharmacotherapeutic Group of (API)	Cytostatic agent: Folic Acid analogue (**L01BA01)**
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Methotrexate 25 mg/ml solution for injection **(MHRA** Approved)
	For generic drugs (me-too status)	Zexate 500mg Injection by Atco (Reg # 047542)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Excella GmbH Nurnberger Strasse 12 D-90537 Feucht Germany
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has also referred to their CEP certificate No. R1-CEP 2000-024-Rev 10 which is verified from EDQM database.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has also referred to their CEP certificate No. R1-CEP 2000-024-Rev 10 which is verified from EDQM database.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted details of formulation development study. Firm has used Methotrexate Injection 25mg/ml (500mg/20mL) manufactured by Cynamid of Great Britan Ltd England as comparator product. Firm has performed testing of comparator product and used its values for developing their own formulation. Firm has provided detailed process of formulation development including results of various experiments to control pH and other parameters.
	Analytical method validation/verification of product	Firm has submitted that the product was initially registered as an import license product and manufactured in Intas Pharmaceuticals India in 2014. After that they file a variation application for replacement of manufacturing site to Onko Ilac Turkey in 2015. During this variation application manufacturing method transfer and analytical method transfer studies were performed. Process validation,

		batch analysis and stability studies were also performed. The application was approved from MoH in 2017.
	Container closure system of the drug product	20mL Type-I clear glass vial (20R transparent glass vial) with 20mm Chlorobuthyl grey rubber stopper and 20mm Aluminium flip-off brown seal
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 51005400, 51005500 and 51005600. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH for 24 months.
Evaluation by PEC[3]:		
Decision: Approved as per Policy for inspection of Manufacturer abroad.		
2531.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	AqVia GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany.
	Name, address of manufacturer(s)	AMW GmbH Birkerfeld 11 83627 Warngau Germany
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original Legalized copy of CoPP (Certificate#. 2678.Ph_12-43-26) issued on 04-12-2019 by Regierung von Oberbayern Maximilanstr 39 80538 Munchen Deutschland. (Google translation: Government of upper Bavaria Maximilianstr Munich Germany. The CoPP confirms the free sale status of the applied product and GMP status of the manufacturer through periodic inspections every 2 years. **GMP:** Firm has submitted Legalized copy of GMP (Certificate#. DE_BY_04_GMP_2018_0087) issued on 01-08-2018 for M/s AMW GmbH Birkerfeld 11 83627 Warngau Germany by Regierung von Oberbayern Maximilanstr 39 80538 Munchen Deutschland. (Google translation: Government of upper Bavaria Maximilianstr Munich Germany.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Product specific sole agency agreement dated 13-03-2020 from AqVida GmbH Kaiser-Wilhelm Str-89 20355 Hamburg Germany.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22158 : 28-10-2019
	Details of fee submitted	PKR 100,000/-: 28-10-2019
	The proposed proprietary name / brand name	**Leugon 11.25mg implant**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each implant contains: 11.25mg Leuprorelin corresponding to 10.72mg Leuprorelin
	Pharmaceutical form of applied drug	Sterile cylindrical rods (diameter 1.5mm, length about 18mm and mass about 38mg prepared by holt melt extrusion
	Pharmacotherapeutic Group of (API)	Gonadotropin releasing hormone analogues: (**L02AE02)**
	Reference to Finished product specifications	In house specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Staladex 10.72 mg Implant (**MHRA** Approved)
	For generic drugs (me-too status)	Lorelin depot 11.25mg injectable. of M/s Amgo Med, islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Bachem AG Haupstr 144 CH-4416 Bubendorf Switzerland.
	Module-III Drug Substance:	Not submitted as per Form 5F requirements
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Module-III Drug Product:	Not submitted as per Form 5F requirement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for drug substance and drug product.
	Container closure system of the drug product	Each implant is individually packed in single dose syringe applicator. The applicator appearing as syringe, consists of three main parts, the body with implant, holder unit and a mandarin and a needle unit. The applicator along with implant is packaged together with desiccant capsule in a sealed polyester/aluminium/ polyethylene pouch.
	Stability study data of drug product, shelf life and storage conditions	Firm has only submitted real time stability study data as per Zone IV-A conditions

Evaluation by PEC[3]:		
• Data of drug substance in module 3 is not submitted as per Form 5F format. • Data of drug product in module 3 is not submitted as per Form 5F format. • Data of Pharmaceutical equivalence is not submitted • Accelerated stability data of drug product is not submitted.		
Decision: Deferred for submission of complete data of drug substance and drug product in Module-3 as per the requirements of Form 5F, further explained by Registration Board in the instant meeting.		
2532.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	Samyang Biopharmaceuticals Corporation 79, Sinildong-ro, Daedeok-gu, Daejeon, Republic of Korea
	Name, address of manufacturer(s)	Samyang Biopharmaceuticals Corporation 79, Sinildong-ro, Daedeok-gu, Daejeon, Republic of Korea
	Name of exporting country	Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted Original Legalized CoPP (Certificate#. 2019-A1-0616) issued on 28-06-2019 by Pharmaceutical policy division, Pharmaceutical safety bureau, Ministry of food and drug safety. The CoPP confirms the free sale status of the applied product and GMP status of the the manufacturer through periodic inspections every 3 years.
	Details of letter of authorization / sole agency agreement	Firm has submitted a notarized copy of Product specific sole agency agreement.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4858 : 30-04-2019
	Details of fee submitted	PKR 50,000/-: 30-04-2019
	The proposed proprietary name / brand name	**Azalid Aqvida Injection 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Azacitidine…..100mg
	Pharmaceutical form of applied drug	Sterile lyophilized powder for suspension for injection packed in one clear glass vial with rubber stopper and an aluminium cap
	Pharmacotherapeutic Group of (API)	pyrimidine analogue, antineoplastic: (**L01BC07)**
	Reference to Finished product specifications	In house specs
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vidaza Injection (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	QOS is submitted as per WHO QOS-PD Template
	Name, address of drug substance manufacturer	Shilpa Medicare Limited Plot No. 33, 33A, 40 to 47, Raichur Industrial Growth Centre Wadloor Road Chicksugur Cross Chicksugur Raichur Karnataka india.
	Module-III Drug Substance:	Not submitted as per Form 5F requirement
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The accelerated stability data is conducted at 25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5ºC ±2ºC for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of pharmaceutical equivalence against the innovator drug product i.e. Vidaza injection. Firm has also performed in use stability studies and compatibility studies of their product as well as the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for drug substance and drug product.
	Container closure system of the drug product	The finished product is filled in colourless type I glass vials sealed with rubber stoppers and aluminium caps, containing 100 mg of azacitidine.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH for 36 months for 1 batch and 24 months for 2 batches.
Evaluation by PEC[3]:		
• Data of drug substance in module 3 is not submitted as per Form 5F format.		
Decision: Deferred for submission of complete data of drug substance in Module-3 as per the requirements of Form 5F, further explained by Registration Board in the instant meeting.		
2533.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor

	Name and address of marketing authorization holder (abroad)	Samyang Biopharmaceuticals Corporation 79, Sinildong-ro, Daedeok-gu, Daejeon, Republic of Korea
	Name, address of manufacturer(s)	Samyang Biopharmaceuticals Corporation 79, Sinildong-ro, Daedeok-gu, Daejeon, Republic of Korea
	Name of exporting country	Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted Original Legalized CoPP (Certificate#. 2019-A1-0615) issued on 28-06-2019 by Pharmaceutical policy division, Pharmaceutical safety bureau, Ministry of food and drug safety. The CoPP confirms the free sale status of the applied product and GMP status of the the manufacturer through periodic inspections every 3 years.
	Details of letter of authorization / sole agency agreement	Firm has submitted a notarized copy of Product specific sole agency agreement.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4857 : 30-04-2019
	Details of fee submitted	PKR 50,000/-: 30-04-2019
	The proposed proprietary name / brand name	**Azalid Aqvida Injection 150mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Azacitidine…..150mg
	Pharmaceutical form of applied drug	Sterile lyophilized powder for suspension for injection packed in one clear glass vial with rubber stopper and an aluminium cap
	Pharmacotherapeutic Group of (API)	pyrimidine analogue, antineoplastic: (**L01BC07)**
	Reference to Finished product specifications	In house specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vidaza Injection (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	QOS is submitted as per WHO QOS-PD Template
	Name, address of drug substance manufacturer	Shilpa Medicare Limited Plot No. 33, 33A, 40 to 47, Raichur Industrial Growth Centre Wadloor Road Chicksugur Cross Chicksugur Raichur Karnataka india.
	Module-III Drug Substance:	Not submitted as per Form 5F requirement
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The

		accelerated stability data is conducted at 25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5ºC ±2ºC for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of pharmaceutical equivalence against the innovator drug product i.e. Vidaza injection. Firm has also performed in use stability studies and compatibility studies of their product as well as the reference product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for drug substance and drug product.
	Container closure system of the drug product	The finished product is filled in colourless type I glass vials sealed with rubber stoppers and aluminium caps, containing 150 mg of azacitidine.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH for 24 months.
Evaluation by PEC[3]:		
• Data of drug substance in module 3 is not submitted as per Form 5F format.		
Decision: Deferred for submission of complete data of drug substance in Module-3 as per the requirements of Form 5F, further explained by Registration Board in the instant meeting.		
2534.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted Original Legalized CoPP (Certificate#. DA/6-110/2016/3675) issued on 18-02-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited.
	Details of letter of authorization / sole agency agreement	Firm has submitted a **copy** of Product specific sole agency agreement.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1198: 19-03-2019
	Details of fee submitted	PKR 50,000/-: 19-03-2019 PKR 50,000/-: 30-04-2020
	The proposed proprietary name / brand name	**Linamide 10mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide…….10mg
	Pharmaceutical form of applied drug	White to off white colored powder is encapsulated in empty hard glatin capsule shells size # 2 (white OP Body & deep Blue OP Cap)
	Pharmacotherapeutic Group of (API)	Other immunosuppressants: (**L04AX)**
	Reference to Finished product specifications	In house specs
	Proposed Pack size	18's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Revlimid Capsule (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	QOS is submitted as per WHO QOS-PD Template
	Name, address of drug substance manufacturer	Mac-Chem Products (India) Pvt. 304, Town Centre Andheri-Kurla Road Andheri (East) Mumbai 400 059 India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of API at accelerated and real time conditions. The real time stability data is conducted as per 25ºC ±2ºC / 60% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for drug substance and drug product.
	Container closure system of the drug product	Alu-Alu blister
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH for 36 months for 1 batch and 24 months for 2 batches.
Evaluation by PEC[3]:		
• Data of pharmaceutical equivalence is not submitted. • Data of comparative dissolution profile is not submitted.		
Decision: Deferred for following submissions: • **Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.** • **Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.**		
2535.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block "C", Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block C, Faisal Town District Lahore. **Validity:** 06-02-2022 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted Original Legalized CoPP (Certificate#. DA/6-110/2016/3674) issued on 18-02-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited.
	Details of letter of authorization / sole agency agreement	Firm has submitted a **copy** of Product specific sole agency agreement.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 1440 : 21-03-2019
	Details of fee submitted	PKR 50,000/-: 19-03-2019 PKR 50,000/-: 30-04-2020
	The proposed proprietary name / brand name	**Linamide 25mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Lenalidomide…….25mg
	Pharmaceutical form of applied drug	Not submitted
	Pharmacotherapeutic Group of (API)	Other immunosuppressants: (**L04AX)**
	Reference to Finished product specifications	In house specs
	Proposed Pack size	18's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Revlimid Capsule (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	QOS have been submitted as per WHO QOS-PD Template
	Name, address of drug substance manufacturer	Mac-Chem Products (India) Pvt. 304, Town Centre Andheri-Kurla Road Andheri (East) Mumbai 400 059 India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per 25°C ±2°C

		/ 60% ± 5% RH for 24 months.
	Module-III Drug Product:	Not submitted as per Form 5F requirement
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation report for drug substance and drug product.
	Container closure system of the drug product	Not submitted
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH for 24 months.

Evaluation by PEC[3]:

- Data of pharmaceutical equivalence is not submitted.
- Data of comparative dissolution profile is not submitted.
- The details of container closure system is not submitted.
- Data of module 3 drug product part is not submitted as per Form 5F requirements.

Decision: Deferred for following submissions:

- **Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.**
- **Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.**
- **Details of container closure system for the applied product.**
- **Complete data of drug product in Module 3 as per the requirements of Form 5F, further explained by Registration Board in the instant meeting.**

M/s Wyeth has submitted the following response dated 25 August 2020.
Dear Sir,

This refers to initial application for registration of Pristiq 50mg Extended Release Tablets submitted by Wyeth Pakistan Limited for registration to the erstwhile Ministry of Health offices in June 2008.

We wish to inform you that since then, there has been some changes that has occurred including change of manufacturer of this imported product. In order to keep the information accurate and up-to-date, we have recently re-submitted our application in compliance to the current CTD requirements vide our letter no. NR/Reg/12/2019 dated 31-October-2019 (copy attached).

At the same time, we have also submitted a new registration application of Pristiq 100mg Extended Release Tablets at your kind offices.

We have also responded to the queries related to dossier evaluation of both applications as communicated to us from your good offices (copies attached).

Please also note that the U.S. Food and Drug Administration (FDA) approved Wyeth's research and innovative product PRISTIQ (desvenlafaxine) in 2008. It's a structurally novel, once-daily serotonin-norepinephrine reuptake inhibitor (SNRI), to treat adult patients with major depressive disorder (MDD).

Therefore, we now request you to kindly consider these applications as new registration applications and consider them for review and approval at the forthcoming meeting of Drug Registration Board.

Accordingly the below mentioned 2 cases are presented before the Board

2536.	**Name, address of Applicant / Importer**	**M/s Wyeth Pakistan Limited. Room No. 002 and 003; PGS Admin Block First Floor B-2 S.I.T.E, Karachi**

	Details of Drug Sale License of importer	**License No:** DHSKDK(Drug)/-1152 **Address:** B-2, S.I.T.E., Room No. 002 & 003 Karachi. **Address of Godown:** NA **Validity:** 21-06-2020. **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Pfizer Australia Pty Ltd Level 17 151 Clarence Street Sydney NSW 2000 Australia
	Name, address of manufacturer(s)	**Manufacturing site:** M/s Pfizer Ireland Pharmaceuticals, Little Connell Newbridge, county Kildare Ireland **Packaging, Labeling & Release for supply site:** Pfizer Manufacturing Deutchland GmbH Mooswaldallee 1 Freiburg 79090 Germany
	Name of exporting country	Australia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original Legalized CoPP (Certificate#. 19/0052) dated 31-01-2019 issued by Therapeutic Goods Administration Australia declaring the free sale of applied product and GMP compliant status of the manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted original sole agent letter from Pfizer Australia Pty Ltd. ABN 50 008 422 348 Level 15-18, 151 Clearance Street Sydney NSW 2000 Australia dated 12-06-2020. The letter specifies that the product license holder authorizes Wyeth Pakistan Limited B-2 SITE Karachi to be the sole agent for Pristiq ER 50mg Tablet.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy No 23104 : 08-11-2019
	Details of fee submitted	PKR 15,000/-: 12-06-2008 PKR 35,000/- : 08-11-2019 PKR 50,000/-: 29-06-2020
	The proposed proprietary name / brand name	**PRISTIQ 50mg Extended Release Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release tablet Contains: Desvenlafaxine Succinate…..50mg
	Pharmaceutical form of applied drug	Light pink square film coated tablets debossed “W” over “50” on flat side.
	Pharmacotherapeutic Group of (API)	SNRI
	Reference to Finished product specifications	In house
	Proposed Pack size	7’s, 14’s, 28’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pristiq ER Tablet **(USFDA** Approved).
	For generic drugs (me-too status)	Desvel XR 50mg Tablet of M/s HILTON PHARMA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Pfizer Asia Manufacturing Pte Ltd. 31 Taus South Ave 6 Singapore 637578
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated and real time conditions. The accelerated stability is conducted at 40ºC±2 ºC / 75% ±5% RH. The real time stability is conducted at 30ºC±2 ºC / 65% ±5% RH 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Applied drug is an innovator product having NDA registration status in FDA, the firm has submitted detailed reports of product development including clinical, and in vitro dissolution studies.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVDC coated polyvinyl chloride PVC film with an aluminium foil lidding or a PVC/Aclar Ultrex 2000 film with an aluminium foil lidding.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data 3 batches 36 months at 30±20C, 75±5%RH and 6 months at 400C±75%RH for three batches.

Evaluation by PEC[3]:

- Evidence of 15,000 fee submitted by the firm could not be confirmed.
- DSL was valid till 21-06-2020, firm has submitted copy of receipt submitted for renewal of DSL dated 12-6-2020.

Discussion: During the proceedings of the meeting, it was revealed that M/s Wyeth Pakistan Limited, Karachi has already applied for this product i.e. Pristiq 50mg Extended Release Tablets with following details:

Manufacturer	Name of drug (s)/ Composition & Therapeutic Group.	Demanded Price/Pack.	Shelf Life.
M/s.Wyeth Pakistan Limited, Karachi/ Manufactured by M/s. Wyeth Pharmaceuticals Co., Puerto Rico. Packed and Released by M/s. Wyeth Taiwan Corporation, Taiwan.	Pristiq 50mg Extended Release Tablets. Each tablet contains:- Desvenlafexaine 50mg.	Rs.291.06/1's. Rs.4074.85/14's.	02years

The case was already discussed in 215 and 222nd meeting of Registration Board.

Decision: Registration Board decided to defer the case with proceedings of 215 and 222nd meeting for further deliberation.

2537.	**Name, address of Applicant / Importer**	**M/s Wyeth Pakistan Limited. Room No. 002 and 003; PGS Admin Block First Floor B-2 S.I.T.E, Karachi**
	Details of Drug Sale License of importer	**License No:** DHSKDK(Drug)/-1152 **Address:** B-2, S.I.T.E., Room No. 002 & 003 Karachi. **Address of Godown:** NA **Validity:** 21-06-2020. **Status:** Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	Pfizer Australia Pty Ltd Level 17 151 Clarence Street Sydney NSW 2000 Australia
	Name, address of manufacturer(s)	**Manufacturing site:** M/s Pfizer Ireland Pharmaceuticals, Little Connell Newbridge, county Kildare Ireland **Packaging, Labeling & Release for supply site:** Pfizer Manufacturing Deutchland GmbH Mooswaldallee 1 Freiburg 79090 Germany
	Name of exporting country	Australia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original Legalized CoPP (Certificate#. 19/0054) dated 31-01-2019 issued by Therapeutic Goods Administration Australia declaring the free sale of applied product and GMP compliant status of the manufacturer
	Details of letter of authorization / sole agency agreement	Firm has submitted original sole agent letter from Pfizer Australia Pty Ltd. ABN 50 008 422 348 Level 15-18, 151 Clearance Street Sydney NSW 2000 Australia dated 12-06-2020. The letter specifies that the product license holder authorizes Wyeth Pakistan Limited B-2 SITE Karachi to be the sole agent for Pristiq ER 50mg Tablet.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy No 23105 : 08-11-2019
	Details of fee submitted	PKR 50,000/- : 08-11-2019 PKR 50,000/-: 29-06-2020
	The proposed proprietary name / brand name	**PRISTIQ 100mg Extended Release Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release tablet Contains: Desvenlafaxine Succinate…..100mg
	Pharmaceutical form of applied drug	Reddish orange square film coated tablets debossed "W" over "100" on flat side.
	Pharmacotherapeutic Group of (API)	SNRI
	Reference to Finished product specifications	In house
	Proposed Pack size	7's, 14's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pristiq ER Tablet **(USFDA** Approved).
	For generic drugs (me-too status)	Desvel XR 50mg Tablet of M/s HILTON PHARMA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Pfizer Asia Manufacturing Pte Ltd. 31 Taus South Ave 6 Singapore 637578
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated and real time conditions. The accelerated stability is conducted at 40ºC±2 ºC / 75% ±5% RH. The real time stability is conducted at 30ºC±2 ºC / 65% ±5% RH 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and

		stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Applied drug is an innovator product having NDA registration status in FDA, the firm has submitted detailed reports of product development including clinical, and in vitro dissolution studies.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVDC coated polyvinyl chloride PVC film with an aluminium foil lidding or a PVC/Aclar Ultrex 2000 film with an aluminium foil lidding.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted three batches long term stability data 3 batches 36 months at 30±20C, 75±5%RH and 6 months at 400C±75%RH for three batches..
Evaluation by PEC[3]:		
• DSL was valid till 21-06-2020, firm has submitted copy of receipt submitted for renewal of DSL dated 12-6-2020.		
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		

b. New cases of local manufacturing

Request of M/s Ferozesons for Priority review of applications submitted on Form 5F submitted against newly granted section

M/s Ferozesons Pharmaceuticals have submitted following applications on CTD format. Firm has submitted that their two tablet sections were approved in 274th meeting of CLB and they were granted approval of two new sections. On the basis of new sections, they are allowed for registration of 10 molecules in each section on priority basis. Firm has submitted as follows

"In view of above approval, we request you to kindly consider "Empagliflozin + Metformin tablet on fast track registration and accordingly add these CTD submissions on priority basis during upcoming DRB meeting."

The cases are evaluated and presented before the Board.

2538.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17091: 13-04-2020

	Details of fee submitted	PKR 20,000/-: 17-02-2020 PKR 30,000/- : 20-08-2020
	The proposed proprietary name / brand name	**EMPAGEN-M 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…500mg
	Pharmaceutical form of applied drug	Yellow, oblong, biconvex tablet having "ferozesons" on one side and break line on other side
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy 5/500 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy 5/500mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-007	EGTab-008	EGTab-009
Batch Size	650 tablet	650 tablet	650 tablet
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	24-04-2019	24-04-2019	24-04-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software.

		• The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[3]:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
2539.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9707: 04-05-2020
	Details of fee submitted	PKR 20,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Pharmaceutical form of applied drug	Yellow oblong, biconvex film coated tablet plain on one side and "*f*" on other side
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy tablets **(USFDA** Approved)
	For generic drugs (me-too status)	Xenglomet 5/1000mg tablet by Hilton Pharma (Reg#093102)
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical

		method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy 5/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy 5/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	EGTab-010	EGTab-011	EGTab-012
Batch Size	650 tablet	650 tablet	650 tablet
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	03-08-2019	03-08-2019	03-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2540.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9705: 04-05-2020
	Details of fee submitted	PKR 20,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Pharmaceutical form of applied drug	Orange, oblong, biconvex film coated tablet having "Ferozesons" on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy tablets **(USFDA** Approved)
	For generic drugs (me-too status)	Xenglomet 12.5/500mg tablet by Hilton Pharma (Reg#093067)
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy 12.5/500 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy 12.5/500mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.
STABILITY STUDY DATA		
Manufacturer of API	**Empagliflozin:**	

	Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-013	EGTab-014	EGTab-015
Batch Size	650 tablet	650 tablet	650 tablet
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	25-06-2019	25-06-2019	25-06-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui

		Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2541.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9706: 04-05-2020
	Details of fee submitted	PKR 20,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Pharmaceutical form of applied drug	Orange, oblong, biconvex film coated tablet plain on one side and "*f*" on other side.

	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy tablets **(USFDA** Approved)
	For generic drugs (me-too status)	Xenglomet 12.5/1000mg tablet by Hilton Pharma (Reg#093068)
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy 12.5/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy 12.5/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-016	EGTab-017	EGTab-018
Batch Size	650 tablet	650 tablet	650 tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	20-09-2019	20-09-2019	20-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022.

		• Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[3]:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
2542.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12838: 13-05-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 5mg Metformin HCl (as extended release layer)…1000mg
	Pharmaceutical form of applied drug	Green, oblong tablet plain on one side and "*f*" on other side.
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. **Metformin**:

		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has developed their formulation as per the reference product in which empagliflozin is used in coating solution to provide immediate release function and the metformin is present in the compressed layer as extended release. Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy XR 5/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy XR 5/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes. The f2 factor value of empagliflozin at all pH is as follows: **pH 1.2**: 58 **pH 4.5:** 54 **pH 6.8:** 69 The f2 factor value of metformin at all pH is as follows: **pH 1.2**: 88 **pH 4.5:** 93 **pH 6.8:** 92
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-019	EGTab-020	EGTab-021
Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	08-05-2019	08-05-2019	08-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2543.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11691: 20-05-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 10mg Metformin HCl (as extended release layer)…1000mg
	Pharmaceutical form of applied drug	Green, oblong tablet plain on one side and "*f*" on other side.
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has developed their formulation as per the reference product in which empagliflozin is used in coating solution to provide immediate release function and the metformin is present in the compressed layer as extended release. Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy XR 10/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy XR 10/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes. The f2 factor value of empagliflozin at all pH is as follows: **pH 1.2**: 68 **pH 4.5:** 52

		pH 6.8: 56 The f2 factor value of metformin at all pH is as follows: **pH 1.2**: 96 **pH 4.5:** 94 **pH 6.8:** 95
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-022	EGTab-023	EGTab-024
Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	12-09-2019	12-09-2019	12-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**:

		• Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[3]:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
2544.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12839: 13-05-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 12.5mg Metformin HCl (as extended release layer)…1000mg
	Pharmaceutical form of applied drug	Blue, oblong tablet plain on one side and "*f*" on other side.
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at

		40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has developed their formulation as per the reference product in which empagliflozin is used in coating solution to provide immediate release function and the metformin is present in the compressed layer as extended release. Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy XR 12.5/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy XR 12.5/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes. The f2 factor value of empagliflozin at all pH is as follows: **pH 1.2**: 52 **pH 4.5:** 63 **pH 6.8:** 62 The f2 factor value of metformin at all pH is as follows: **pH 1.2**: 73 **pH 4.5:** 96 **pH 6.8:** 94
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-025	EGTab-026	EGTab-027

Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	30-04-2019	30-04-2019	30-04-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2545.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11692: 20-05-2020
	Details of fee submitted	PKR 50,000/-: 17-02-2020
	The proposed proprietary name / brand name	**EMPAGEN-M XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 25mg Metformin HCl (as extended release layer)…1000mg
	Pharmaceutical form of applied drug	Green, oblong tablet plain on one side and "*f*" on other side.
	Pharmacotherapeutic Group of (API)	Anti diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy XR tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 24 months. **Metformin**: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has developed their formulation as per the reference product in which empagliflozin is used in coating solution to provide immediate release function and the metformin is present in the compressed layer as extended release. Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Synjardy XR 10/1000 of Boehringer. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Synjardy XR 10/1000mg tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release in all the three medium shows greater than 85% release in 15 minutes. The f2 factor value of empagliflozin at all pH is as follows: **pH 1.2**: 50 **pH 4.5:** 53 **pH 6.8:** 52

		The f2 factor value of metformin at all pH is as follows: **pH 1.2**: 93 **pH 4.5:** 98 **pH 6.8:** 97
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for both drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co, Ltd Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province China. **Metformin**: Ipca Laboratories Limited, H-4, M.1.0.C., Waluj Aurangabad, Maharashtra India.		
API Lot No.	**Empagliflozin:** E-20180425-D01-E06-01 **Metformin**: 18117 ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EGTab-028	EGTab-029	EGTab-030
Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	28-10-2019	28-10-2019	28-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** • Firm has submitted copy of DML (No. Liao 20150223) issued by Food and Drug Administration of Liaoning Province China. The certificate is valid till December 20, 2022. • Firm has submitted copy of GMP certificate issued by Fuxin Food and Drug Administration. The certificate is valid till 27-09-2020. **Metformin**: • Firm has submitted copy of letter of License retention with products (License No. 25-AD/070) issued by FDA Maharashtra. The letter contains list of approved products

		including metformin hydrochloride. The letter is valid till 31-03-2024. • Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Maharashtra dated 31-08-2018. The certificate is valid till 27-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** • Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of emapgliflozin 650gm M/s Beijing Huikang Pharmaceuticals Manufactured by Fuxin Long Rui Pharmaceuticals China issued by Ad (I&E) DRAP field office. The license was issued on 13-04-2018. • Firm has submitted copy of commercial invoice dated 08-05-2018 specifying import of 650g Empagliflozin. **Metformin**: Firm has submitted copy of commercial invoice dated 12-10-2018 specifying import of 2500Kg Metformin HCl. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC[3]:		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
2546.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 24-01-2018 concludes very good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 27-07-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23543: 12-11-2019
	Details of fee submitted	PKR 50,000/-: 12-11-2019
	The proposed proprietary name / brand name	**CONOFEN Tablet 5/200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Phenylephrine HCl……5mg Ibuprofen……..200mg
	Pharmaceutical form of applied drug	Yellow colored film coated tablet, oval (Biconvex) with bisect line on one side and plain on other side
	Pharmacotherapeutic Group of (API)	NSAID in combination with sympathomimetic amine
	Reference to Finished product specifications	Manufacturer's specs
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nurofen Sinus Pain Relief 200mg/5mg Tablets **(MHRA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted data of pharmaceutical equivalence as well as comparative dissolution profile

	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.		
API Lot No.	**Phenylephrine HCl:** PEH-180101Y1 **Ibuprofen:** ZIBU18-009		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	17-02-2019	17-02-2019	17-02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018 • Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Phenylephrine HCl:** Copy of GMP certificate (No. GD20150448) issued by CFDA china is submitted by the firm. The certificate is valid till 07-12-2020. **Ibuprofen:** Copy of GMP certificate of M/s Zenith Chemical Industries (Pvt) Limited dated 22-05-2019 issued on the basis of inspection dated 06-12-2018 is submitted by the firm. The certificate is issued by Additional Director DRAP Lahore.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Phenylephrine HCl:** Firm has submitted copy of commercial invoice specifying import of 308.25g of phenylephrine dated 10-05-2018. The invoice is signed by AD (I&E) DRAP Islamabad. **Ibuprofen:** Firm has submitted copy of invoice specifying purchase of 250Kg Ibuprofen from Zenith Chemical Industries Lahore dated 26-06-2018.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed*."	Pharmaceutical equivalence dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.
Submit summary of the results of comparative dissolution profile in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed. For comparative dissolution profile, the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms - Dissolution Profile Comparisons may be followed".*	Comparative dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.
Scientific rationale for development of tablet having bisect line on one side of the tablet.	Our applied Drug products (Conofen Tablets 5/200mg and Conofen Tablets 10/200mg) compressed on oval (bi-convex) shaped having bisect line on one side and plain on other side which is our available punch design and the applied drug products are stable with afore mentioned punch design. Moreover, we had submitted the stability studies data of three batches (Trials) on accelerated and real-Time stability conditions (as per decision of 293rd meeting of Drug Registration Board.
Provide acceptance criteria in terms of the amount of dissolved active ingredient "Q" for dissolution test at 15 minutes.	Acceptance criteria in terms of the amount of dissolved active ingredient Q = NLT 80% for dissolution test of conofen tablets at 15minutes for both Phenylephrine HCL and Ibuprofen.

Decision: Deferred for following submissions:

- **Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.**
- **Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.**

2547.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 24-01-2018 concludes very good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 27-07-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23542: 12-11-2019
	Details of fee submitted	PKR 50,000/-: 12-11-2019
	The proposed proprietary name / brand name	**CONOFEN Tablet 10/200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Phenylephrine HCl……10mg Ibuprofen……..200mg
	Pharmaceutical form of applied drug	Light brown colored film coated tablet, oval (Biconvex) with bisect line on one side and plain on other side
	Pharmacotherapeutic Group of (API)	NSAID in combination with sympathomimetic amine
	Reference to Finished product specifications	Manufacturer's specs
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Advil Congestion Relief Tablet 200mg/10mg **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted data of pharmaceutical equivalence as well as comparative dissolution profile
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.		
API Lot No.	**Phenylephrine HCl:** PEH-180101Y1 **Ibuprofen:** ZIBU18-009		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	02-02-2019	02-02-2019	02-02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018

		• Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Phenylephrine HCl:** Copy of GMP certificate (No. GD20150448) issued by CFDA china is submitted by the firm. The certificate is valid till 07-12-2020. **Ibuprofen:** Copy of GMP certificate of M/s Zenith Chemical Industries (Pvt) Limited dated 22-05-2019 issued on the basis of inspection dated 06-12-2018 is submitted by the firm. The certificate is issued by Additional Director DRAP Lahore.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Phenylephrine HCl:** Firm has submitted copy of commercial invoice specifying import of 308.25g of phenylephrine dated 10-05-2018. The invoice is signed by AD (I&E) DRAP Islamabad. **Ibuprofen:** Firm has submitted copy of invoice specifying purchase of 250Kg Ibuprofen from Zenith Chemical Industries Lahore dated 26-06-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.*"	Pharmaceutical equivalence dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.
Submit summary of the results of comparative dissolution profile in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed. For comparative dissolution profile, the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid*	Comparative dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.

Oral Dosage Forms - Dissolution Profile Comparisons may be followed".	
Scientific rationale for development of tablet having bisect line on one side of the tablet.	Our applied Drug products (Conofen Tablets 5/200mg and Conofen Tablets 10/200mg) compressed on oval (bi-convex) shaped having bisect line on one side and plain on other side which is our available punch design and the applied drug products are stable with afore mentioned punch design. Moreover, we had submitted the stability studies data of three batches (Trials) on accelerated and real-Time stability conditions (as per decision of 293rd meeting of Drug Registration Board.
Provide acceptance criteria in terms of the amount of dissolved active ingredient "Q" for dissolution test at 15 minutes.	Acceptance criteria in terms of the amount of dissolved active ingredient Q = NLT 80% for dissolution test of conofen tablets at 15minutes for both Phenylephrine HCL and Ibuprofen.

Decision: Deferred for following submissions:

- **Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.**
- **Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.**

2548.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 24-01-2018 concludes very good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 27-07-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 96: 03-02-2020
	Details of fee submitted	PKR 50,000/-: 21-01-2020
	The proposed proprietary name / brand name	**HISTAB Tablet 25mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Diphenhydramine HCl……25mg
	Pharmaceutical form of applied drug	Red colored film coated tablet, round with bisect line on one side and plain on other side
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use (R06AA02)
	Reference to Finished product specifications	BP specs
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Uncoated tablets:**

		Diphenhydramine hydrochloride 25mg tablet **(MHRA** Approved), (**Health Canada** Approved) **Film coated tablet:** Benadryl Tablet by Johnson & Johnson Consumer Inc. available at FDA OTC (dailymed) database
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Supriya Lifescience Ltd. A-5/2, Lote Parshuram Industrial Area, MIDC, Khed-415722 Taluka Khed District Ratnagiri Mahrashtra state India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of comparative dissolution profile of their product with the reference product i.e. Benadryl Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The drug release was above 85% in 15 minutes in all medias.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Supriya Lifescience Ltd. A-5/2, Lote Parshuram Industrial Area, MIDC, Khed-415722 Taluka Khed District Ratnagiri Mahrashtra state, India
API Lot No.	SLL/DPH/0915051
Description of Pack (Container closure system)	Alu-Alu Blister packed in card box unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	01-03-2019	01-03-2019	01-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018 • Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 67649/2018/11/25185) issued by FDA Maharashtra. The certificate is valid till 04-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice, airway bill, form 3 and form 7 dated 06-11-2015 specifying import of 100Kg of diphenhydramine hydrochloride. The invoice is not signed by AD (I&E) DRAP Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. as per the decision of 293rd meeting of Registration Board, which states that "*Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed*."	Firm has submitted results of Pharmaceutical Equivalence of their product against the reference product Benadryl Tablet 25mg manufactured by Johnson & Johnson, UK.

Provide scientific justification for use of 3% overage in the formulation of trial batches in section 3.2.P.2.2.2.	The 3% overage is included to compensate for process losses during manufacturing. The batch size is lab scale of 1500 Tablets. The amount of active is 25 mg per Tablet and 3% overage amount to 0.75mg per Tablet respectively. The overage ensures a content uniformity within range as per USP 2018.
Provide scientific rationale for development of tablet having bisect line on one side of the tablet.	We have already got some products in round shaped without a bisect line. Therefore in order to differentiate between the products and to eliminate chances of mixing, the punch and dies set with a bisect line was selected.
Justify why the commercial invoice for import of drug substance is not attested by AD (I&E), DRAP Islamabad office.	Our Active Pharmaceutical Ingredient (Diphenhydramine Hydrochloride) bearing Invoice no. SLL/EXP/794/15-16, cleared from DRAP dated: 25-11-2015. At that time Mr. Atiq Ul Bari was authorized for the purpose of issuance of Clearance. Firm has now submitted copy of commercial invoice which is cleared by AD (I&E) DRAP dated 02-12-2015.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2549.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued dated: 14-06-2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 22-06-2018 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23997: 15-11-2019
	Details of fee submitted	PKR 50,000/-: 14-11-2019
	The proposed proprietary name / brand name	**ERTU Tablet 5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic acid)……5mg
	Pharmaceutical form of applied drug	Pink coloured triangular shaped film coated tablet, debossed SAMI on one side and break line on the other side.
	Pharmacotherapeutic Group of (API)	Anti-diabetic

	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Luoyang Town, Wujin District, Changzhou Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Steglatro Tablet manufactured by Merck Sharp Dohme. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The drug release was above 85% in 15 minutes in all medias. Firm also calculated factor f2 which was above 50.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Luoyang Town, Wujin District, Changzhou Jiangsu China.
API Lot No.	ETG 20190101
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tablet	2500 tablet	2500 tablet
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	16-03-2019	16-03-2019	16-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "TEFOD (Tenofovir Alafenamide) 25mg Tablets" which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of this product Date of inspection: 28th January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of Drug Manufacturing License (S 20160130) of M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. The certificate is valid till 31-12-2020. GMP certificate (No. JS20180935) issued by CFDA is also verified online.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to Import drugs for clinical trial, examination, test or analysis" specifying import of 0.8Kg ertugliflozin. Firm has submitted copy of commercial invoice dated 25-01-2019 specifying import of 0.8Kg ertugliflozin along with impurities and working standard. The commercial invoice is not attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Submit data in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted analytical method validation report for validation of the method of analysis for both drug substances.

Submit data in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed."	Firm has submitted comparative analysis report comparing the results of all quality tests for their own product as well as the Steglatro tablet. Firm has also submitted results of comparative dissolution of both products at all the three recommended pH.
Scientific rationale for development of tablet having break line on one side of the tablet.	The reference product is not scored, however score line was suggested for our product. The purpose of score was not for splitting the tablet into two equal doses but only to make differentiation with other existing products. No impact was observed on the dissolution of product, therefore the generic tablet will be scored.
Justify selection of dissolution parameters i.e. USP apparatus-II paddle with 100rpm and 0.1N HCl as dissolution medium, since the dissolution parameters declared by USFDA in its review of innovator product i.e. Steglatro are USP apparatus-I (Basket) with 100 rpm and acetate buffer pH 4.5 as dissolution medium.	Ertugliflozin falls in BCS class I and its solubility is pH independent which is also confirmed by the CDP report that it achieves 80% Q in 15 minutes at all pH ranges. Initially we performed dissolution by using following following parameters Media: 0.1N HCl RPM: 100 Apparatus: II (Paddle) Time 30 min. Stability batches were analysed at 0,1,2,3,4 & 6 months on in house testing but after reviewing the FDA drug approval, we revised our testing method and continue the real time stability studies by following method. Media: Acetate buffer (pH 4.5) RPM: 100 Apparatus: I (Basket) Time 15 min. Results from both methods are found similar and no impact observed in the results due to change in dissolution parameters.
Justify the dissolution parameters i.e. NLT 85% in 30 minutes, since the dissolution specifications of the innovator product is NLT (Q) in 15 minutes.	Firm has not provided any specific clarification but have submitted revised testing method and specifications in which the dissolution time is 15 minutes.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data as per USFDA recommended dissolution conditions at 15 minutes at initial and one-month time point at both accelerated and real time stability conditions for 2 batches.

2550.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued dated: 14-06-2018

	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 22-06-2018 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23996: 15-11-2019
	Details of fee submitted	PKR 50,000/-: 14-11-2019
	The proposed proprietary name / brand name	**ERTU Tablet 15mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin (as L-Pyroglutamic acid)……15mg
	Pharmaceutical form of applied drug	Red coloured triangular shaped film coated tablet, debossed SAMI on one side and break line on the other side.
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Steglatro tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Luoyang Town, Wujin District, Changzhou Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis,

		justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Steglatro Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The drug release was above 85% in 15 minutes in all medias. Firm also calculated factor f2 which was above 50.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. Daixi Street Luoyang Town, Wujin District, Changzhou Jiangsu China.		
API Lot No.	ETG 20190101		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2500 tablet	2500 tablet	2500 tablet
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	27-03-2019	27-03-2019	27-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "TEFOD (Tenofovir Alafenamide) 25mg Tablets" which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of this product Date of inspection: 28th January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of Drug Manufacturing License (S 20160130) of M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co. Ltd. The certificate is valid till 31-12-2020. GMP certificate (No. JS20180935) issued by CFDA is also verified online.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to Import drugs for clinical trial, examination, test or analysis" specifying import of 0.8Kg ertugliflozin. Firm has submitted copy of commercial invoice dated 25-01-2019 specifying import of 0.8Kg ertugliflozin along with impurities and working standard. The commercial invoice is not attested by AD (I&E) DRAP field office.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Submit data in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted analytical method validation report for validation of the method of analysis for both drug substances.
Submit data in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed."	Firm has submitted comparative analysis report comparing the results of all quality tests for their own product as well as the Steglatro tablet. Firm has also submitted results of comparative dissolution of both products at all the three recommended pH.
Scientific rationale for development of tablet having break line on one side of the tablet.	The reference product is not scored, however score line was suggested for our product. The purpose of score was not for splitting the tablet into two equal doses but only to make differentiation with other existing products. No impact was observed on the dissolution of product, therefore the generic tablet will be scored.
Justify selection of dissolution parameters i.e. USP apparatus-II paddle with 100rpm and 0.1N HCl as dissolution medium, since the dissolution parameters declared by USFDA in its review of innovator product i.e. Steglatro are USP apparatus-I (Basket) with 100 rpm and acetate buffer pH 4.5 as dissolution medium.	Ertugliflozin falls in BCS class I and its solubility is pH independent which is also confirmed by the CDP report that it achieves 80% Q in 15 minutes at all pH ranges. Initially we performed dissolution by using following following parameters Media: 0.1N HCl RPM: 100 Apparatus: II (Paddle) Time 30 min. Stability batches were analysed at 0,1,2,3,4 & 6 months on in house testing but after reviewing the FDA drug approval, we revised our testing method and continue the real time stability studies by following method. Media: Acetate buffer (pH 4.5) RPM: 100 Apparatus: I (Basket) Time 15 min.

	Results from both methods are found similar and no impact observed in the results due to change in dissolution parameters.
Justify the dissolution parameters i.e. NLT 85% in 30 minutes, since the dissolution specifications of the innovator product is NLT (Q) in 15 minutes.	Firm has not provided any specific clarification but have submitted revised testing method and specifications in which the dissolution time is 15 minutes.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data as per USFDA recommended dissolution conditions at 15 minutes at initial and one-month time point at both accelerated and real time stability conditions for 2 batches.

2551.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, SITE, Karachi.**
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**Macter International:** Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP. **English Pharmaceutical:** GMP certificate issued based on inspection dated 06-01-2018
	Evidence of approval of manufacturing facility	Firm (M/s English Pharmaceuticals) has submitted copy of renewal of DML letter dated 09-03-2015 specifying Dry powder injectable vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 15806 dated 02-07-2020
	Details of fee submitted	Rs.50,000/- Dated 07-05-2020
	The proposed proprietary name / brand name	**VANCOMAC 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin (as HCl) …… 500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vancomycin 500mg Powder for Solution for Infusion **MHRA** Approved
	For generic drugs (me-too status)	Vanbact 500mg Injection by NabiQasim (Reg # 070682)
	Name and address of API manufacturer.	M/s Livzon Syntpharm Co. Ltd. (Zhuhai FTZ) Zhuhai Free Trade Zone, Wanzai, Zhuhai Gd. Wanfang Industrial Park, Macun Area, Jiaozuo, Henan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions**.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation pf analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Livzon Syntpharm Co. Ltd. (Zhuhai FTZ) Zhuhai Free Trade Zone, Wanzai, Zhuhai Gd. Wanfang Industrial Park, Macun Area, Jiaozuo, Henan.		
API Lot No.	HAF1809029.		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	VMI-021	VMI-022	VCI-001
Batch Size	34602 vials	8685 vials	3100 vials
Manufacturing Date	02-2019	10-2019	07-2019
Date of Initiation	27-02-2019	26-10-2019	10-07-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (No. GD20180856) issued by China Food and Drug Administration has been submitted. The submitted certificate is valid till 31-07-2023.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice specifying import of 20Kg Vancomycin HCl sterile USP. The invoice is attested by AD (I&E) DRAP Lahore dated 10-12-2018 for batch # HAF1809029.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator[3]

Shortcomings communicated	Response by the firm
Submit contract manufacturing agreement between the applicant and contract manufacturer.	Firm has submitted copy of contract manufacturing agreement
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit mentioned in Module 1 under section 1.5.2 is vancomycin hydrochloride eq to vancomycin 1g, while the submitted fee is for vancomycin hydrochloride eq to vancomycin 500mg. Clarification is required in this regard.	It was a typographic error. Correct strength is now being submitted under section 1.5.2.
Commitments in module 1 should be submitted by the applicant instead of contract manufacturer.	Firm has submitted all commitments
Quality overall summary (QoS) should be submitted by filling the WHO template or the template approved by Registration Board in its 293rd meeting instead of attaching documents from module 3. Complete drug substance part in Module 3 is not submitted.	Firm has submitted QOS as per WHO QOS PD template
Provide detailed analytical method for drug substance as well drug product.	Firm has submitted detailed analytical method for drug substance and drug product.
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted analytical method verification report for drug substance.

Specify the exact batch number of drug substance used in the manufacturing of stability batches.	HAF1809029.
Submit results of batch analysis in section 3.2.S.4.4 to comply the decision of 293rd meeting of Registration Board, which states that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture".	COA of relevant batches has been provided
Submit stability study data of drug substance in section 3.2.S.7.	Stability study data of 3 batches is submitted,
Provide scientific justification for use of 2.5% overage in the formulation.	The 2.5% overage was a typo error and was mistakenly mentioned under the master formula. We have not used any overage and are also submitting our BMR for stability batches as evidence that the formulation was dispensed without any overage.
Submit information in section 3.2.P.1 to comply the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".	Firm has submitted details of the diluent as per the innovator product
Submit data in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	Firm has submitted pharmaceutical equivalence of their product against the reference product Vancocine Injection.
Submit the data of compatibility studies in section 3.2.P.2.6 to comply the decision of 293rd meeting of Registration Board, which states that "Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	Firm has submitted results of description, pH, clarity of solution and assay of their product after reconstitution with the accompanying diluent.
Justify why the test for uniformity of dosage unit, water determination and content of vancomycin are not included in finished product specification, since these tests are included in the USP monograph. Provide detailed analytical procedure in section 3.2.P.5.2.	Finished product specifications as per USP monograph have been submitted
Provide detailed protocols for validation of bioassay for vancomycin hydrochloride injection and also provide validation report summarized results for each testing parameter as per the relevant ICH / FDA / WHO guidelines in section 3.2.P.5.3.	Validation studies of Bio Assay has been submitted by the firm

Justify why the validation / verification of analytical chromatographic method provided under content of vancomycin in the USP monograph is not performed.	Firm has submitted verification studies report for the drug substance.
Provide justification of specifications of the finished drug product in section 3.2.P.5.6.	Firm has submitted justification of specifications
Provide COA of primary / secondary reference standard including source and lot number in section 3.2.P.6.	Firm has submitted COA of reference standard and standardized working standard
Provide the details regarding type of glass vial, material of construction and colour of rubber stopper in section 3.2.P.7.	Firm has submitted details of container closure system for their product.
Justify the use of 20cc glass vials for the applied product, since the innovator products are supplied in 10ml glass vials.	The word 20cc in container closure system was a typo error and actually we are using 10 ml glass vials as per the innovator product.
Provide batch size in terms of number of vials for all the stability batches.	Firm has submitted revised stability data sheets including batch size in terms of number of vials.
Provide the data of in-use stability studies in section 3.2.P.8 as per the decision of 293rd meeting of Registration Board, which states that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided."	Since the applied formulation is meant for immediate administration upon reconstitution hence in-use stability is not required.
Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 293rd meeting, which includes the following documents: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted the documents with stability data as per the guidelines of 293rd meeting of Registration Board.
Provide batch manufacturing record for the stability batches.	Firm has submitted BMR of all the three batches

Decision: Registration Board decided to approve registration of VANCOMAC 500mg Injection by M/s Macter International Limited. F-216, SITE, Karachi, contract manufactured by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.

2552.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, SITE, Karachi.**

	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**Macter International:** Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP. **English Pharmaceutical:** GMP certificate issued based on inspection dated 06-01-2018
	Evidence of approval of manufacturing facility	Firm (M/s English Pharmaceuticals) has submitted copy of renewal of DML letter dated 09-03-2015 specifying Dry powder injectable vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 15807 dated 02-07-2020
	Details of fee submitted	Rs.50,000/- Dated 07-05-2020
	The proposed proprietary name / brand name	**VANCOMAC 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin (as HCl) …… 1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vancomycin 500mg Powder for Solution for Infusion **MHRA** Approved
	For generic drugs (me-too status)	Vanbact 500mg Injection by NabiQasim (Reg # 070682)
	Name and address of API manufacturer.	M/s Livzon Syntpharm Co. Ltd. (Zhuhai FTZ) Zhuhai Free Trade Zone, Wanzai, Zhuhai Gd. Wanfang Industrial Park, Macun Area, Jiaozuo, Henan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions**.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Livzon Syntpharm Co. Ltd. (Zhuhai FTZ) Zhuhai Free Trade Zone, Wanzai, Zhuhai Gd. Wanfang Industrial Park, Macun Area, Jiaozuo, Henan.		
API Lot No.	HAF1702010		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	VMI-018	VMI-019	VCI-002
Batch Size	14800 vials	21500 vials	4385 vials
Manufacturing Date	01-2018	06-2018	07-2019
Date of Initiation	19-01-2018	10-07-2018	15-07-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (No. GD20180856) issued by China Food and Drug Administration has been submitted. The submitted certificate is valid till 31-07-2023.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice specifying import of 70Kg Vancomycin HCl sterile USP. The invoice is

		attested by AD (I&E) DRAP Lahore dated 30-03-2017 for batch # HAF1702010.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator[3]

Shortcomings communicated	**Response by the firm**
Submit contract manufacturing agreement between the applicant and contract manufacturer.	Firm has submitted copy of contract manufacturing agreement
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit mentioned in Module 1 under section 1.5.2 is vancomycin hydrochloride eq to vancomycin 1g, while the submitted fee is for vancomycin hydrochloride eq to vancomycin 500mg. Clarification is required in this regard.	It was a typographic error. Correct strength is now being submitted under section 1.5.2.
Commitments in module 1 should be submitted by the applicant instead of contract manufacturer.	Firm has submitted all commitments
Quality overall summary (QoS) should be submitted by filling the WHO template or the template approved by Registration Board in its 293rd meeting instead of attaching documents from module 3. Complete drug substance part in Module 3 is not submitted.	Firm has submitted QOS as per WHO QOS PD template
Provide detailed analytical method for drug substance as well drug product.	Firm has submitted detailed analytical method for drug substance and drug product.
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted analytical method verification report for drug substance.
Specify the exact batch number of drug substance used in the manufacturing of stability batches.	HAF1809029.
Submit results of batch analysis in section 3.2.S.4.4 to comply the decision of 293rd meeting of Registration Board, which states that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture".	COA of relevant batches has been provided
Submit stability study data of drug substance in section 3.2.S.7.	Stability study data of 3 batches is submitted,
Provide scientific justification for use of 2.5% overage in the formulation.	The 2.5% overage was a typo error and was mistakenly mentioned under the master formula.

	We have not used any overage and are also submitting our BMR for stability batches as evidence that the formulation was dispensed without any overage.
Submit information in section 3.2.P.1 to comply the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".	Firm has submitted details of the diluent as per the innovator product
Submit data in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	Firm has submitted pharmaceutical equivalence of their product against the reference product Vancocine Injection.
Submit the data of compatibility studies in section 3.2.P.2.6 to comply the decision of 293rd meeting of Registration Board, which states that "Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	Firm has submitted results of description, pH, clarity of solution and assay of their product after reconstitution with the accompanying diluent.
Justify why the test for uniformity of dosage unit, water determination and content of vancomycin are not included in finished product specification, since these tests are included in the USP monograph. Provide detailed analytical procedure in section 3.2.P.5.2.	Finished product specifications as per USP monograph have been submitted
Provide detailed protocols for validation of bioassay for vancomycin hydrochloride injection and also provide validation report summarized results for each testing parameter as per the relevant ICH / FDA / WHO guidelines in section 3.2.P.5.3.	Validation studies of Bio Assay has been submitted by the firm
Justify why the validation / verification of analytical chromatographic method provided under content of vancomycin in the USP monograph is not performed.	Firm has submitted verification studies report for the drug substance.
Provide justification of specifications of the finished drug product in section 3.2.P.5.6.	Firm has submitted justification of specifications
Provide COA of primary / secondary reference standard including source and lot number in section 3.2.P.6.	Firm has submitted COA of reference standard and standardized working standard
Provide the details regarding type of glass vial, material of construction and colour of rubber stopper in section 3.2.P.7.	Firm has submitted details of container closure system for their product.

Justify the use of 20cc glass vials for the applied product, since the innovator products are supplied in 10ml glass vials.	The word 20cc in container closure system was a typo error and actually we are using 10 ml glass vials as per the innovator product.
Provide batch size in terms of number of vials for all the stability batches.	Firm has submitted revised stability data sheets including batch size in terms of number of vials.
Provide the data of in-use stability studies in section 3.2.P.8 as per the decision of 293rd meeting of Registration Board, which states that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided."	Since the applied formulation is meant for immediate administration upon reconstitution hence in-use stability is not required.
Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 293rd meeting, which includes the following documents: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted the documents with stability data as per the guidelines of 293rd meeting of Registration Board.
Provide batch manufacturing record for the stability batches.	Firm has submitted BMR of all the three batches

Decision: Registration Board decided to approve registration of VANCOMAC 1g Injection by M/s Macter International Limited. F-216, SITE, Karachi, contract manufactured by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.

2553.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, SITE, Karachi.**
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**Macter International:** Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP. **English Pharmaceutical:** GMP certificate issued based on inspection dated 06-01-2018
	Evidence of approval of manufacturing facility	Firm (M/s English Pharmaceuticals) has submitted copy of renewal of DML letter dated 09-03-2015 specifying Dry powder injectable vial (General) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 15753 dated 26-08-2019
	Details of fee submitted	Rs.50,000/- Dated 26-08-2019
	The proposed proprietary name / brand name	**COLMIT 1MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium …… 1MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection **MHRA** Approved
	For generic drugs (me-too status)	Colitec 1MIU Injection by Rotex Pharma (Reg # 092316)
	Name and address of API manufacturer.	• M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions**.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang.		
API Lot No.	HN180401		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	CLI-001	CLI-002	CLI-001
Batch Size	46511 vials	46511 vials	31000 vials
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	28-03-2019	28-03-2019	25-03-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of Drug Manufacturing License has been submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice specifying import of 8Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP Lahore dated 19-11-2018 for batch # HN180401
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Remarks of Evaluator[3]

Shortcomings communicated	Response by the firm

Submit contract manufacturing agreement between the applicant and contract manufacturer.	Firm has submitted copy of contract manufacturing agreement
Commitments in module 1 should be submitted by the applicant instead of contract manufacturer.	Firm has submitted all commitments
Quality overall summary (QoS) should be submitted by filling the WHO template or the template approved by Registration Board in its 293rd meeting instead of attaching documents from module 3. Complete drug substance part in Module 3 is not submitted.	Firm has submitted QOS as per WHO QOS PD template
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted analytical method verification report for drug substance.
Submit results of batch analysis in section 3.2.S.4.4 to comply the decision of 293rd meeting of Registration Board, which states that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture".	COA of relevant batches has been provided
Submit stability study data of drug substance in section 3.2.S.7.	Stability study data of the drug substance is submitted as per zone IV-A conditions.
Provide scientific justification for use of ±5% overage in the formulation.	The 2.5% overage was a typo error and was mistakenly mentioned under the master formula. We have not used any overage and are also submitting our BMR for stability batches as evidence that the formulation was dispensed without any overage.
Submit information in section 3.2.P.1 to comply the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".	Firm has submitted details of the diluent as per the innovator product
Submit data in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed.	Firm has submitted pharmaceutical equivalence of their product against the comparator product.

Submit the data of compatibility studies in section 3.2.P.2.6 to comply the decision of 293rd meeting of Registration Board, which states that "Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	Firm has submitted results of description, pH, clarity of solution and assay of their product after reconstitution with the accompanying diluent.
Justify why the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.	Firm has submitted revised specifications as per USP monograph which includes these tests.
Provide detailed protocols for validation of bioassay for colistimethate sodium injection and also provide validation report summarized results for each testing parameter as per the relevant ICH / FDA / WHO guidelines in section 3.2.P.5.3.	Validation studies of Bio Assay has been submitted by the firm
Provide justification of specifications of the finished drug product in section 3.2.P.5.6.	Firm has submitted justification of specifications
Provide COA of primary / secondary reference standard including source and lot number in section 3.2.P.6.	Firm has submitted COA of reference standard and standardized working standard
Provide the details regarding type of glass vial, material of construction and colour of rubber stopper in section 3.2.P.7.	Firm has submitted details of container closure system for their product.
Justify the use of 15cc glass vials for the applied product, since the innovator / reference products are supplied in 7ml or 10ml glass vials.	The word 15cc in container closure system was a typo error and actually we are using 10 ml glass vials as per the Reference product.
Provide batch size in terms of number of vials for all the stability batches.	Firm has submitted revised stability data sheets including batch size in terms of number of vials.
Provide the data of in-use stability studies in section 3.2.P.8 as per the decision of 293rd meeting of Registration Board, which states that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided."	Since the applied formulation is meant for immediate administration upon reconstitution hence in-use stability is not required.
Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 293rd meeting, which includes the following documents: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted the documents with stability data as per the guidelines of 293rd meeting of Registration Board.

• Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
Provide batch manufacturing record for the stability batches.	Firm has submitted BMR of all the three batches

Decision: Registration Board decided to approve registration of COLMIT 1MIU Injection by M/s Macter International Limited. F-216, SITE, Karachi, contract manufactured by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.

Case no. 05 Registration applications of drugs for which stability study data is submitted

a. New cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2554	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Denzol 30mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….30mg	Form 5 08-01-2015 PKR 20,000/- (08-01-2015) + PKR 100,000/- (08-01-2015)	Dexilant capsule (**USFDA** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable level of GMP compliance
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

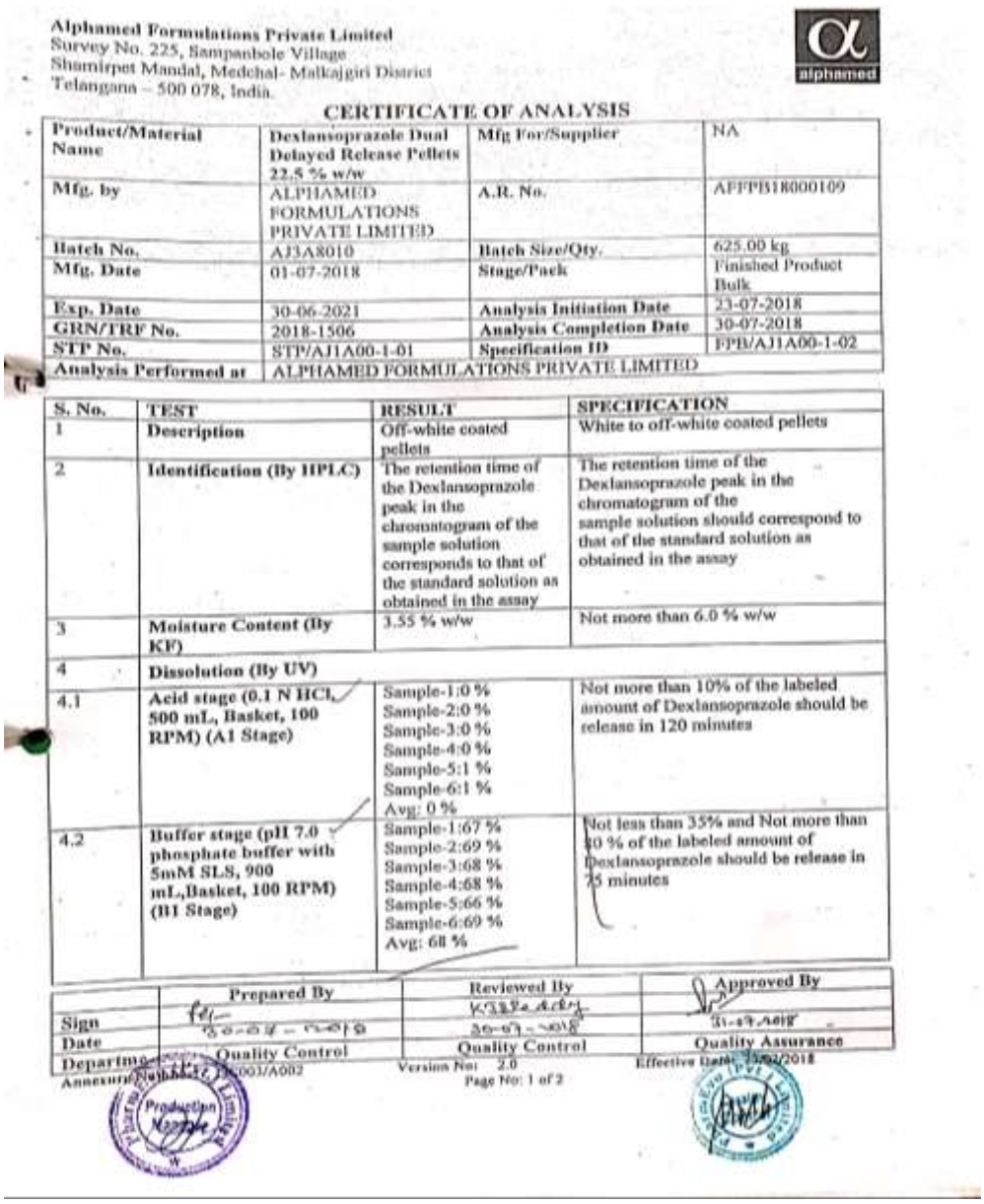
STABILITY STUDY DATA			
Drug	Denzol 30mg Capsule		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Alphamed Formulations Private Limited. Sy No. 225, Sampanbole village Shamirpet Mandal, Medchal-Malkajgiri District Telangana India.		
API Lot No.	AJ3A8010		
Description of Pack (Container closure system)	White to off white coated pellets filled in size No. 3 gelatin capsule having off white cap and off white body and packed into Alu Alu foil in printed unit carton.		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD-2428-01-T	18PD-2429-02-T	18PD-2430-03-T

Batch Size	2500 Capsule	2500 Capsule	2500 Capsule
Manufacturing Date	Oct-2018	Oct-2018	Oct-2018
Date of Initiation	20-10-2018	20-10-2018	20-10-2018
No. of Batches	03		
Date of Submission	Dy.# 7196 dated 27-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Telangana dated 03-5-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 08-08-2018 specifying import of 4Kg pellets
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

- Firm has submitted two different COA from Alphamed which are totally contradictory with each other in terms of dissolution profiles.



Alphamed Formulations Private Limited
Survey No. 225, Sampanbole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

alphamed

CERTIFICATE OF ANALYSIS

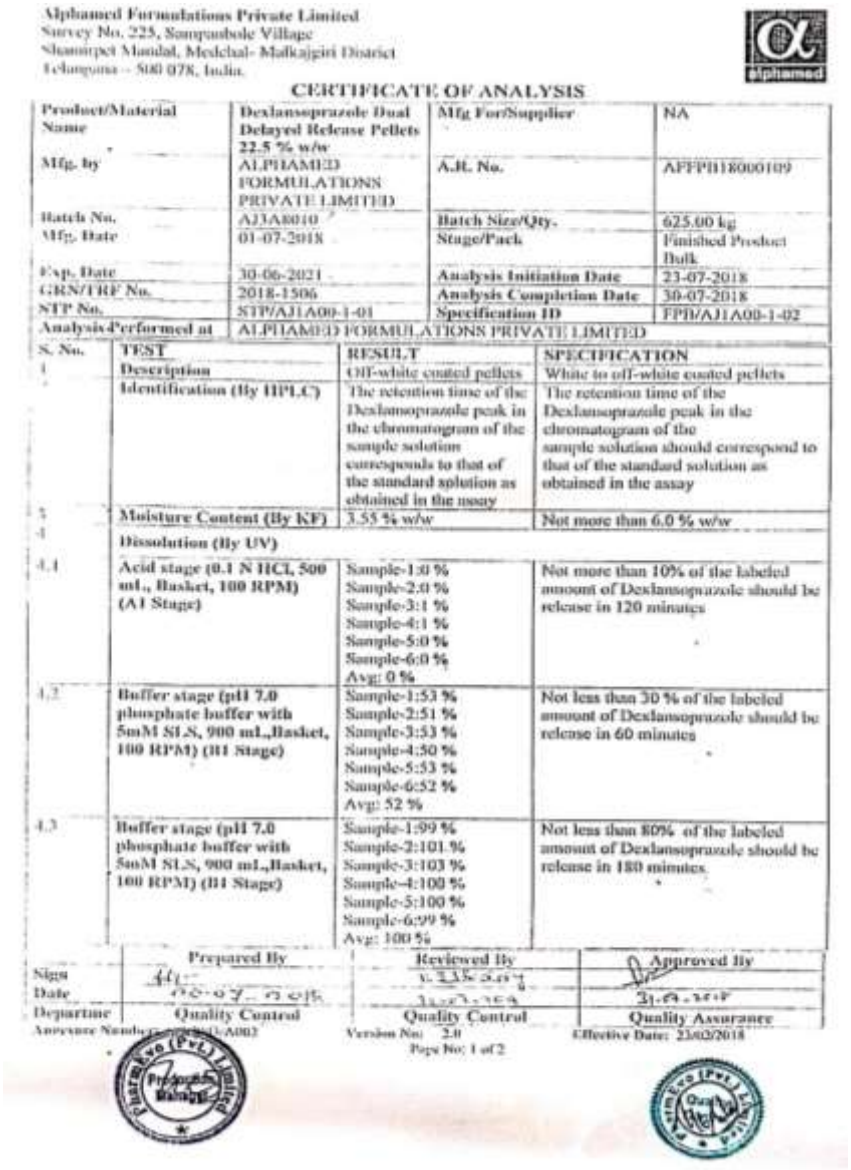
Product/Material Name	**Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w**	**Mfg For/Supplier**	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	**A.R. No.**	APFPB18000109
Batch No.	AJ3A8010	**Batch Size/Qty.**	625.00 kg
Mfg. Date	01-07-2018	**Stage/Pack**	Finished Product Bulk
Exp. Date	30-06-2021	**Analysis Initiation Date**	23-07-2018
GRN/TRF No.	2018-1506	**Analysis Completion Date**	30-07-2018
STP No.	STP/AJ1A00-1-01	**Specification ID**	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Off-white coated pellets	White to off-white coated pellets
2	**Identification (By HPLC)**	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	**Moisture Content (By KF)**	3.55 % w/w	Not more than 6.0 % w/w
4	**Dissolution (By UV)**		
4.1	**Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)**	Sample-1:0 % Sample-2:0 % Sample-3:0 % Sample-4:0 % Sample-5:1 % Sample-6:1 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	**Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)**	Sample-1:67 % Sample-2:69 % Sample-3:68 % Sample-4:68 % Sample-5:66 % Sample-6:69 % Avg: 68 %	Not less than 35% and Not more than 80 % of the labeled amount of Dexlansoprazole should be release in 75 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date			
Department	Quality Control	Quality Control	Quality Assurance

Annexure No: FPB/QC/003/A002 Version No: 2.0 Effective Date: 15/02/2018
Page No: 1 of 2

- As per the first COA (submitted along with stability data) attached above, the dissolution testing of pellets was carried out at acid stage and buffer stage at pH 7.0. At the buffer stage, the acceptance criteria are **NLT 35% and NMT 80% in 75 minutes.** As per the analytical report generated by the firm the acceptance criteria for buffer stage was **NLT 80% without specifying time**. Further the finished product specification of the firm NLT 75% in 75 minutes is also contradictory to the COA of pellets manufacturer. After letter of shortcoming, firm has submitted following COA



Alphamed Formulations Private Limited
Survey No. 225, Sampabole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

CERTIFICATE OF ANALYSIS

Product/Material Name	Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w	Mfg For/Supplier	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	A.R. No.	AFFPH18000109
Batch No.	AJ3A8010	Batch Size/Qty.	625.00 kg
Mfg. Date	01-07-2018	Stage/Pack	Finished Product Bulk
Exp. Date	30-06-2021	Analysis Initiation Date	23-07-2018
GRN/TRF No.	2018-1506	Analysis Completion Date	30-07-2018
STP No.	STP/AJ1A00-1-01	Specification ID	FPD/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Off-white coated pellets	White to off-white coated pellets
2	Identification (By HPLC)	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	Moisture Content (By KF)	3.55 % w/w	Not more than 6.0 % w/w
4	Dissolution (By UV)		
4.1	Acid stage (0.1 N HCL, 500 ml., Basket, 100 RPM) (A1 Stage)	Sample-1:0 % Sample-2:0 % Sample-3:1 % Sample-4:1 % Sample-5:0 % Sample-6:0 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 ml.,Basket, 100 RPM) (B1 Stage)	Sample-1:53 % Sample-2:51 % Sample-3:53 % Sample-4:50 % Sample-5:53 % Sample-6:52 % Avg: 52 %	Not less than 30 % of the labeled amount of Dexlansoprazole should be release in 60 minutes
4.3	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 ml.,Basket, 100 RPM) (B1 Stage)	Sample-1:99 % Sample-2:101 % Sample-3:103 % Sample-4:100 % Sample-5:100 % Sample-6:99 % Avg: 100 %	Not less than 80% of the labeled amount of Dexlansoprazole should be release in 180 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date	26-07-2018	30-07-2018	31-07-2018
Departme	Quality Control	Quality Control	Quality Assurance

Annexure Number: Annexure/QA/A002 Version No: 2.0 Effective Date: 23/03/2018
Page No: 1 of 2

- The second COA of alphamed submitted by the firm (Pharmevo) is of the same batch AJ3A8010 signed on the same dates but with totally different release specification. As per new COA the average release of pellets at pH 7.0 is 100% while that mentioned in previous COA was 68%. As per new COA the testing of pellets at pH 7.0 is conducted at two different stages at two specifications i.e. NLT 30% in 60 minutes and NLT 80% in 180 minutes.
- Further, since the firm has submitted that their finished product specifications is NLT 75% in 75 minutes and as per the response provided by firm, the release of pellets was more than 80% in 75 minutes, while as per the COA of pellets release is NLT 80% in 180 minutes.
- Further the firm has not performed testing of pellets at pH 5.5 as per the requirements of Registration Board.

Shortcoming communicated	Response received by the firm
Scientific justification is required for the adaptation of dissolution specification (NLT 75% in 75 minutes) in buffer stage for finished product in the light of general monographs of USP/BP and FDA guidance on "Dissolution Testing of Immediate Release Solid Oral Dosage Forms"	Firm has submitted that as per USFDA recommended dissolution method the end time point is 120 minutes for acid as well as buffer stage. We have set specification NLT 75% after 75 minutes in buffer stage as when we tested the pellets at initial stage the release was more than 80% in 75 minutes so we shortened the specified time point of 120 minutes to 75 minutes.

Decision of 291st meeting of Registration Board:
Deferred for following:

- Scientific justification of submission of 2 different certificate of analysis from the pellets manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.
- Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.
- Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.

Response by the firm:

Decision of Registration Board	Response by the firm
Scientific justification of submission of 2 different certificate of analysis from the pellets manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.	The firm has submitted that the API manufacturer conducted the testing with three different procedures and provided us with all the COA's. During submission we erroneously attached CoA different from our development method. We are now enclosing the test procedures, CoA from the supplier as well as testing of finished product.
Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.	Initially the dissolution time point at phosphate buffer was set in accordance to USFDA dissolution method. As in the FDA dissolution database the end time point is 120 minutes for acid and buffer stage. We would like to mention that initially we find our results more than 75% in 75 minutes and we considered the results as baseline of Q value. It may be noted that we further extended the test till 120 minutes and results were found to be more than 90%. Furthermore for verification of release pattern, comparative study with innovator product Dexilant capsule has also been conducted and the results found comparable i.e. more than 75% in 75 minutes on both products.
Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.	We initially set the dissolution specification for pellets i.e. in acid condition, buffer stage condition, but we did not performed testing at pH 5.5 before filling of pellets. But as per the decision of Registration Board we have then performed dissolution testing at pH 5.5 and submitting the results. We also commit to perform this test in all new received commercial lots of dexlansoprazole.

If agreed, the case may be forwarded for panel inspection. The panel may be requested to verify the dissolution testing of pellets at pH 5.5 for confirmation of dual delayed release action.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2555	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western	Denzol 60mg Capsule	Form 5 08-01-2015 PKR 20,000/-	Dexilant capsule (**USFDA** Approved)

	Industrial zone, Port Qasim, Karachi.	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg	(08-01-2015) + PKR 100,000/- (08-01-2015) (**DUPLICATE DOSSIER)**	Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable level of GMP compliance
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Denzol 60mg Capsule		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Alphamed Formulations Private Limited. Sy No. 225, Sampanbole village Shamirpet Mandal, Medchal-Malkajgiri District Telangana India.		
API Lot No.	AJ3A8010		
Description of Pack (Container closure system)	White to off white coated pellets filled in size No. 3 gelatin capsule having off white cap and off white body and packed into Alu Alu foil in printed unit carton.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD-2425-01-T	18PD-2426-02-T	18PD-2427-03-T
Batch Size	2500 Capsule	2500 Capsule	2500 Capsule
Manufacturing Date	Sep-2018	Sep-2018	Sep-2018
Date of Initiation	30-10-2018	30-10-2018	30-10-2018
No. of Batches	03		
Date of Submission	Dy.# 7195 dated 27-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Telangana dated 03-5-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 08-08-2018 specifying import of 4Kg pellets

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

- Firm has submitted two different COA from Alphamed which are totally contradictory with each other in terms of dissolution profiles.

Alphamed Formulations Private Limited
Survey No. 225, Sampanbole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

alphamed

CERTIFICATE OF ANALYSIS

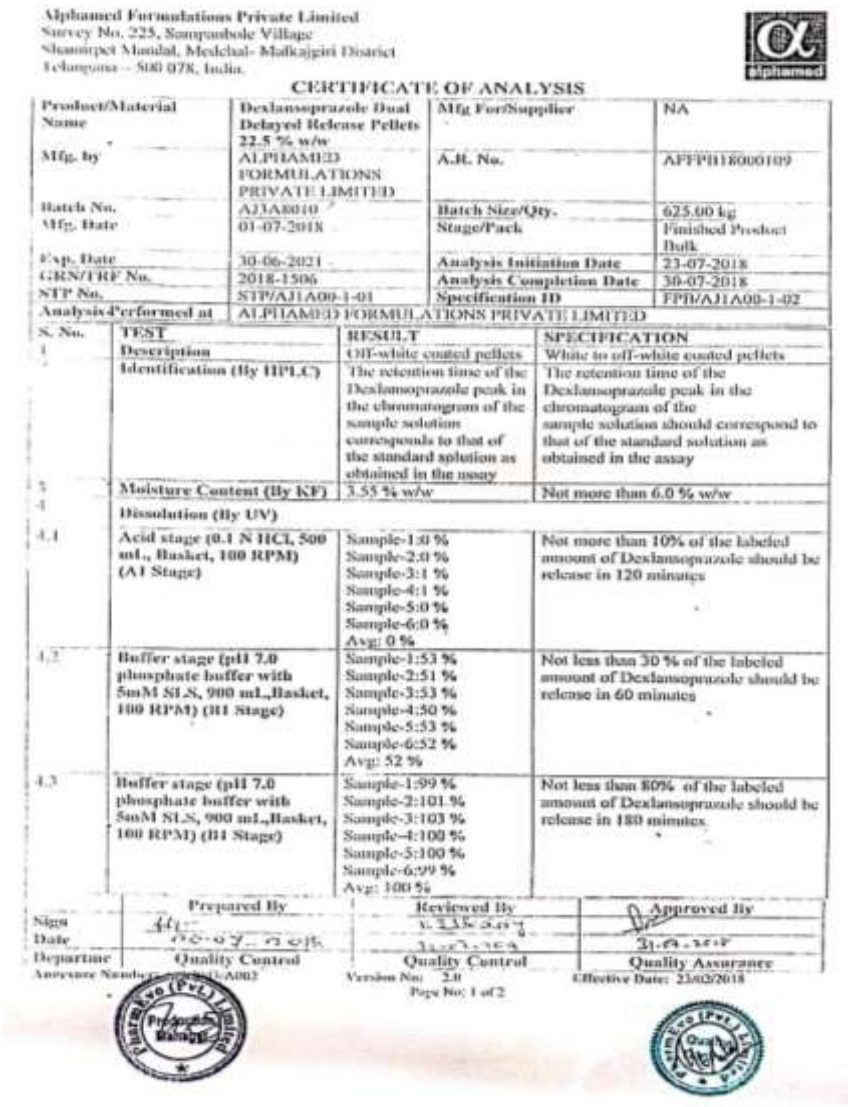
Product/Material Name	**Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w**	**Mfg For/Supplier**	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	**A.R. No.**	AFFPB18000109
Batch No.	AJ3A8010	**Batch Size/Qty.**	625.00 kg
Mfg. Date	01-07-2018	**Stage/Pack**	Finished Product Bulk
Exp. Date	30-06-2021	**Analysis Initiation Date**	23-07-2018
GRN/TRF No.	2018-1506	**Analysis Completion Date**	30-07-2018
STP No.	STP/AJ1A00-1-01	**Specification ID**	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Off-white coated pellets	White to off-white coated pellets
2	**Identification (By HPLC)**	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	**Moisture Content (By KF)**	3.55 % w/w	Not more than 6.0 % w/w
4	**Dissolution (By UV)**		
4.1	**Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)**	Sample-1:0 % Sample-2:0 % Sample-3:0 % Sample-4:0 % Sample-5:1 % Sample-6:1 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	**Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)**	Sample-1:67 % Sample-2:69 % Sample-3:68 % Sample-4:68 % Sample-5:66 % Sample-6:69 % Avg: 68 %	Not less than 35% and Not more than 80 % of the labeled amount of Dexlansoprazole should be release in 75 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date			
Department	Quality Control	Quality Control	Quality Assurance

Annexure No: F/QC/003/A002 Version No: 2.0 Page No: 1 of 2 Effective Date: 23/02/2018

- As per the first COA (submitted along with stability data) attached above, the dissolution testing of pellets was carried out at acid stage and buffer stage at pH 7.0. At the buffer stage, the acceptance criteria are **NLT 35% and NMT 80% in 75 minutes.** As per the analytical report generated by the firm the acceptance criteria for buffer stage was **NLT 80% without specifying time**. Further the finished product specification of the firm NLT 75% in 75 minutes is also contradictory to the COA of pellets manufacturer. After letter of shortcoming, firm has submitted following COA



Alphamed Formulations Private Limited
Survey No. 225, Sampanbole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

CERTIFICATE OF ANALYSIS

Product/Material Name	Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w	Mfg For/Supplier	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	A.R. No.	AFFPB18000109
Batch No.	AJ3A8010	Batch Size/Qty.	625.00 kg
Mfg. Date	01-07-2018	Stage/Pack	Finished Product Bulk
Exp. Date	30-06-2021	Analysis Initiation Date	23-07-2018
GRN/TRF No.	2018-1506	Analysis Completion Date	30-07-2018
STP No.	STP/AJ1A00-1-01	Specification ID	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Off-white coated pellets	White to off-white coated pellets
2	Identification (By HPLC)	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	Moisture Content (By KF)	3.55 % w/w	Not more than 6.0 % w/w
4	Dissolution (By UV)		
4.1	Acid stage (0.1 N HCl, 500 ml., Basket, 100 RPM) (A1 Stage)	Sample-1:0 % Sample-2:0 % Sample-3:1 % Sample-4:1 % Sample-5:0 % Sample-6:0 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 ml.,Basket, 100 RPM) (B1 Stage)	Sample-1:53 % Sample-2:51 % Sample-3:53 % Sample-4:50 % Sample-5:53 % Sample-6:52 % Avg: 52 %	Not less than 30 % of the labeled amount of Dexlansoprazole should be release in 60 minutes
4.3	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 ml.,Basket, 100 RPM) (B1 Stage)	Sample-1:99 % Sample-2:101 % Sample-3:103 % Sample-4:100 % Sample-5:100 % Sample-6:99 % Avg: 100 %	Not less than 80% of the labeled amount of Dexlansoprazole should be release in 180 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date	30-07-2018		31-7-2018
Departme	Quality Control	Quality Control	Quality Assurance

Version No: 2.0 Effective Date: 23/07/2018
Page No: 1 of 2

- The second COA of alphamed submitted by the firm (Pharmevo) is of the same batch AJ3A8010 signed on the same dates but with totally different release specification. As per new COA the average release of pellets at pH 7.0 is 100% while that mentioned in previous COA was 68%. As per new COA the testing of pellets at pH 7.0 is conducted at two different stages at two specifications i.e. NLT 30% in 60 minutes and NLT 80% in 180 minutes.
- Further, since the firm has submitted that their finished product specifications is NLT 75% in 75 minutes and as per the response provided by firm, the release of pellets was more than 80% in 75 minutes, while as per the COA of pellets release is NLT 80% in 180 minutes.
- Further the firm has not performed testing of pellets at pH 5.5 as per the requirements of Registration Board.

Shortcoming communicated	Response received by the firm
Scientific justification is required for the adaptation of dissolution specification (NLT 75% in 75 minutes) in buffer stage for finished product in the light of general monographs of USP/BP and FDA guidance on "Dissolution Testing of Immediate Release Solid Oral Dosage Forms"	Firm has submitted that as per USFDA recommended dissolution method the end time point is 120 minutes for acid as well as buffer stage. We have set specification NLT 75% after 75 minutes in buffer stage as when we tested the pellets at initial stage the release was more than 80% in 75 minutes so we shortened the specified time point of 120 minutes to 75 minutes.

Decision of 291st meeting of Registration Board:
Deferred for following:

- Scientific justification of submission of 2 different certificate of analysis from the pellets manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.
- Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.
- Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.

Response by the firm:

Decision of Registration Board	Response by the firm
Scientific justification of submission of 2 different certificate of analysis from the pellets manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.	The firm has submitted that the API manufacturer conducted the testing with three different procedures and provided us with all the COA's. During submission we erroneously attached CoA different from our development method. We are now enclosing the test procedures, CoA from the supplier as well as testing of finished product.
Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.	Initially the dissolution time point at phosphate buffer was set in accordance to USFDA dissolution method. As in the FDA dissolution database the end time point is 120 minutes for acid and buffer stage. We would like to mention that initially we find our results more than 75% in 75 minutes and we considered the results as baseline of Q value. It may be noted that we further extended the test till 120 minutes and results were found to be more than 90%. Furthermore for verification of release pattern, comparative study with innovator product Dexilant capsule has also been conducted and the results found comparable i.e. more than 75% in 75 minutes on both products.
Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.	We initially set the dissolution specification for pellets i.e. in acid condition, buffer stage condition, but we did not performed testing at pH 5.5 before filling of pellets. But as per the decision of Registration Board we have then performed dissolution testing at pH 5.5 and submitting the results. We also commit to perform this test in all new received commercial lots of dexlansoprazole.

If agreed, the case may be forwarded for panel inspection. The panel may be requested to verify the dissolution testing of pellets at pH 5.5 for confirmation of dual delayed release action.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Denzol (Dexlansoprazole) 30mg and 60mg Capsules by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Reference No: F.1-2/2020-PEC dated 6th July, 2020
Investigation Date and Time: 22nd July, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:
Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi for registration of Denzol (Dexlansoprazole) 30mg & Denzol (Dexlansoprazole) 60mg Capsules and constituted a three member panel to investigate the authenticity /

genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

16. Prof. Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board).
17. Dr. Saif-ur-Rehman Khattak, Director/ FGA, CDL, Karachi.
18. Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Sr. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Dexlansoprazole API including approval from DRAP?	The firm has imported Dexlansoprazole 4.0Kg vide Invoice No. GE052/2018 dated August 1, 2018from M/s Alphamed formulations (Pvt). Ltd for the manufacturing of lab scale batches of Dexlansoprazole 30mg and 60mg Capsules. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the import of Dexlansoprazole, reference standard and impurity standards?	Firm has documents confirming the import of Dexlansoprazole, The API working standard was imported at the time of import of the API whereas the impurity standards imported later on.
4.	Do you have certificate of Analysis of the API, reference standard and impurity standards?	The firm has certificates of analysis for API, Working standard of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Drug Control Administration, Government of Telangana, India.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method, however, no degradation products are reported by the manufacturer. Process related impurities have been quantified during stability studies.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some quantities of the API and working standard, however they have consumed all the impurity standards.

11.	Have you used pharmaceutical grade excipients?	The only excipient used is hard gelatine shells.
12.	Do you have documents confirming the import of the used excipients?	Firm has documents conforming the import of gelatine shells.
13.	Do you have test reports and other records on the excipients used?	Test reports are available on gelatine shells.
14.	Do you have written and authorized protocols for the development of Dexlansoprazole 30mg and 60mg Capsules?	The firm has written and authorized protocols for the development of Dexlansoprazole 30mg and 60mg Capsules.
15.	Have you performed Drug-excipient Compatibility studies?	Not applicable.
16.	Have you performed comparative Dissolution studies?	The firm has performed comparative dissolution profile of Dexlansoprazole 30mg and 60mg Capsule with Dexilant Capsule 30mg and 60mg manufactured by M/s Takeda Pharmaceutical Co. Ltd. respectively. Similarity factor for Dexlansoprazole 30mg Capsule are as follows: Buffer pH 7.0 (55.240). Similarity factor for Dexlansoprazole 60mg Capsule are as follows: Buffer pH 7.0 (52.237).
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment available in product development section for development of Dexlansoprazole 30mg & 60mg Capsules?	These are ready to fill pellets which were filled using ZJT-40 automatic filling machine that is present in the commercial facility. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product Development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration/ re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development currently with suitable knowledge and training in product development. 02 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Dexlansoprazole 30mg and 60mg Capsules as required?	The firm has manufactured three stability batches for the stability studies of: Dexlansoprazole 30mg Capsule with Batch Numbers: 18PD-2428-01-T 18PD-2429-02-T 18PD-2430-03-T Dexlansoprazole 60mg Capsule with Batch Numbers: 18PD-2425-01-T 18PD-2426-02-T 18PD-2427-03-T All batches of both strengths have batch size of 2500 capsules.

23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing batch size is according to DRAP guidelines
24.	Do you have complete record of Production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies have not been done, however, validation of the method has been performed.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Dexlansoprazole and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Dexlansoprazole and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation studies.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show audit trail reports on Dexlansoprazole testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Accelerated stability testing is complete whereas in real time studies 12 months has been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Dexlansoprazole 30mg & 60mg Capsules production and analysis?	The firm has valid calibration status for the equipment used in Dexlansoprazole Capsules production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.
37.	**Specific Queries by PEC/Board** To verify the dissolution testing of pellets at pH 5.5 for confirmation of dual delayed release action.	As per direction of the PEC results of dissolution testing of the pellets at pH 5.5 were reviewed. It was concluded that the results lie within the limits (less than 35% in three hours).

Conclusions:

14. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Denzol 30mg/60mg (Dexlansoprazole) Capsules are verifiable to satisfactory level.

15. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Denzol 30mg/60mg (Dexlansoprazole) Capsules.

Recommendations:

1. Since Denzol 30mg/60mg (Dexlansoprazole) Capsules are modified release (delayed release) capsules therefore, post registration bioequivalence studies should be conducted on the product before marketing.
2. Firm must developed specific identification test for dexlansoprazole in the pallets and the finished product.
3. The firm may kindly be granted necessary registration of Denzol 30mg/60mg (Dexlansoprazole) Capsules.

Note: The firm has submitted written undertaking for post registration bioequivalence studies on the capsules (copy enclosed).

Decision: Registration Board decided to approve registration of Denzol (Dexlansoprazole) 30mg and 60mg Capsules with Innovator's specifications by M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2556	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Omrax 12.5mg Tablet Each film coated tablet contains: Omarigliptin….12.5mg (Antidiabetic)	Form 5D 14-03-2016 PKR 50,000/- (14-03-2016) (**DUPLICATE DOSSIER)**	Marizeb Tablet by MSD (**PMDA Japan** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable level of GMP compliance
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Omrax 12.5mg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Ruyuan HEC Pharm Co. Ltd, Ruyuan County, Shaoguan City Guandong Province PR China		
API Lot No.	RD201803001		
Description of Pack (Container closure system)	Yellow color round biconvex shape film coated tablet plain from both sides and packed into Alu Alu foil in printed unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD-2460-01-T	18PD-2461-02-T	18PD-2462-03-T

Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Nov-2018	Nov-2018	Nov-2018
Date of Initiation	31-12-2018	31-12-2018	31-12-2018
No. of Batches	03		
Date of Submission	Dy.# 6151 dated 15-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted: • copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated 31-05-2016 • Copy of letter and establishment inspection report by FDA dated 13-11-2015
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 20-04-2018 specifying import of 0.5Kg Omarigliptin along with 20mg impurity A and B each.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

Shortcoming communicated	Response received by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining the value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. Moreover FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading **DISSOLUTION ACCEPTANCE CRITERIA** that *for immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes.*	Firm has submitted that we have set the dissolution specification NLT 75% as per USFDA and USP. In all provided stability reports the dissolution results are more than 80% on all intervals and in both conditions which indicates that all results are meeting the USP criteria S1 i.e. Q+5. Accelerated stability data dissolution results

Batch No.	0 month	3 month	6month
18PD-2460-01-T	99.37	92.26	98.58
18PD-2461-02-T	100.42	87.02	98.07
18PD-2462-03-T	89.4	87.1	97.9

	Real time stability data dissolution results Batch No. | 0 month | 3 month | 6month 18PD-2460-01-T | 99.37 | 87.35 | 89.01 18PD-2461-02-T | 100.42 | **86.76** | 90.24 18PD-2462-03-T | 89.4 | 92.7 | 97.01 **The exact BCS class of Omarigliptin is not yet identified by PMDA Japan. As per the literature, the solubility of omarigliptin is 543mg/L which makes it an intermediate to high soluble drug. Other gliptins like sitagliptin, vildagliptin, trelagliptin etc are all BCS-III class drugs. As per the USFDA guidelines the value of Q for such drugs should be 80% and for dissolution testing at S-1 level the dissolution limit will become 85% (i.e. Q+5%).** • **Out of trend (OOT) results can be seen although all results are still within acceptable criteria / specifications.** • **Some results at the borderline of acceptance criteria with 6 months data makes it scientifically difficult to predict the shelf life for 24 months.** • **Since this is a once weekly antidiabetic drug and the drug release from each unit will help to control the glycemic levels for whole week that's why the dissolution results of this particular drug plays very important role.**
Submit the latest GMP certificate of the API manufacturer by the relevant regulatory authority of the country of origin.	Firm has again submitted the same inspection report of FDA dated **13-11-2015** and copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated **31-05-2016**.
Justify the finished product specification without the test for content uniformity.	Firm has submitted that they are not performing content uniformity test on new drug product at initial stage but after getting registration from DRAP after inspection on commercial batches we include the test of content uniformity as per guidelines.
Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	Firm has submitted that they have selected apparatus **2 paddle** method and for rpm the range value of 50 to 75 rpm given we have selected **50 rpm**. Time point for immediate release products in USP BP JP and also FDA is given as 30 miutes so we have adopted this **30 minute** end point for our study. Dissolution medium selection water and dilute hydrochloric acid, buffers in pH range of 1.2 to 7.5 are given. But as omarigliptin is Japanese product son we have considered **0.01N HCl** as dissolution medium. As results founded well within

	specification we have adopted this dissolution medium. **Firm has not specified the pH of dissolution medium used. Further the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH while the firm has used 0.01N HCl which has pH 2.0.**
Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and solubility	Firm has submitted that the exact crystal form of omarigliptin used in stability batches in Form-V. Firm has also submitted copy of declaration provided by API manufacturer. **The review report / Deliberation result report of the PMDA Japan approved product Marizeb** (http://www.pmda.go.jp/drugs/2015/P20151007002/170050000_22700AMX01014000_A100_2.pdf Accessed on 23-08-2019) **specifies under the heading Quality materials/<Outline of submitted materials>/API/Characteristics as *"The drug substance is recognized in five crystal forms. The production method produces only crystalline form-I (anhydride) which is stable at room temperature"***

Decision of 291st meeting of Registration Board:

Deferred for following:

- Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.
- Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from the reference product [i.e. NLT 75% after 30 minutes].
- Scientific justification of the Out of Trend (OOT) results of dissolution data.
- Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.
- Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.

Response by the firm:

1. Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.

Firm has submitted a copy of GMP certificate (No. 2018047) issued by Shaoguan Food and Drug Administration China. The certificate is valid till 04-12-2021.

2. Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from the reference product [i.e. NLT 75% after 30 minutes].

Firm has submitted that that stability study at 9 month interval as per specifications NLT 75% (Q); (Q+5% = 80%) in 30 minutes has been conducted and results were found to be within specifications which is indicative of the pattern for dissolution throughout the shelf-life. The firm has also submitted 9th month long term stability data for Omrax 12.5mg Tablet and Omrax 25mg Tablet.

3. Scientific justification of the Out of Trend (OOT) results of dissolution data.

Firm has submitted that "Dissolution results at 3rd and 6th month interval of stability study data submitted in DRAP were found well within specifications. However, variations observed in Dissolution results were specifically due to the weight variation of tablet for each batch. It may be noted that weight variation of tablets for each batch lies within the defined limits as stated in 978 (2040) Weight Variation USP35 (copy attached) and same can be verified through Assay results for each batch during all stability intervals. (Summary of stability results is enclosed for your easy reference).

Furthermore, we have followed USP for acceptance criteria of dissolution test, which allows to continue dissolution testing till three stages (i.e. S1, S2 & S3) stated in USP General Chapter <711> Dissolution.

Therefore, it is evident from dissolution results obtained during stability testing of product are within acceptable limits of S1 stage and declared as normal pattern. However, if in case the results obtained exceed acceptable limit of S1 stage, it is pertinent to note that dissolution testing can be continued till S2 and/or S3 stage as well. If the results then exceed acceptable limits of S2 & S3 stage as well then only it may be considered as OOS which in this case is not relevant as all the results were found within acceptable limits of S1 stage".

4. Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.

Firm has submitted that "We have developed In House method for the dissolution testing of product according to (1092) The Dissolution Procedure: Development and Validation.
Dissolution apparatus 2 paddle method and 50 rpm was selected wherein range value of 50 or 75rpm was mentioned in the reference (copy attached). Time point for immediate release products as stated in USP, BP, JP and US-FDA is 30minutes, therefore we have adopted 30minutes as end point of our study. Water, dilute Hydrochloric Acid and buffers in the pH range of 1.2 to 7.5 were used as dissolution medium.
After a thorough evaluation of solubility of Omarigliptin Tablets, we have considered 0.01N HCl as dissolution medium and same was adopted for dissolution testing parameter in stability studies.
In order to verify solubility profile and release pattern of our product, we have also performed dissolution study in all recommended mediums as mentioned in ICH & EMA and US-FDA guidelines (i.e. pH 1.2, pH 4.5 and pH 6.8). Further, Dissolution Profile study was performed in Buffer pH 2.0 (i.e. 0.01N HCl) as well to justify that there is no significant difference occurring in Buffer pH 2.0 (i.e. 0.01N HCl) & Buffer pH 6.8, which ultimately proves that formulation of Omarigliptin and selected dissolution medium are compatible and accurate".

5. Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.

Firm has submitted that "In the patent of international application published under the Patent Cooperation Treaty (PCT), published date: 2nd March 2017, Patent # WO 2017/032705 A1, it is clearly mentioned that Omarigliptin form-V is more stable.
This patent states that "the known polymorphic forms of Omarigliptin do not seem to be adequately stable under pharmaceutically acceptable conditions and/or tend to convert into each other. Such a conversion of polymorphs often results in an unpredictable behavior of the pharmaceutically active agent with regard to its in-vivo and/or in-vitro properties such as solubility, bioavailability and stability (shelf life)"
It further states ahead "Thus it was an object of the present invention to overcome the drawbacks of the above mentioned prior forms and to provide omarigliptin which is present in a pure and/or stable form. Further, omarigliptin should be provided in a form that can be easily produced also on an industrial scale."
This patent further states in summary "The above objectives are unexpectedly achieved by the provision of a polymorphic form of omarigliptin which is designated omarigliptin form-V"
Conclusion:
This can easily be concluded from above mentioned facts that form-V of Omarigliptin does not have any negative effect on product safety, bioavailability / in-vivo characteristics which may be the risks in other polymorphic forms. Due to this reason we selected this form for generic product development.
Further, comparative study against known omarigliptin crystal form I and V have been performed by API manufacturer M/s Ruyuan HEC Pharm Co. Ltd. and results from the studies proves that "Omarigliptin crystal form V is more stable than the known crystal form I of Omarigliptin, and more suitable for solid preparation application. It is beneficial to improving the bioavailability of the drug, to counteracting the problems of uneven content, purity reduction and the like caused by factors such as time, temperature and humidity".
If agreed, the case may be forwarded for panel inspection and the panel may be requested to verify the following:

- The crystal form V of the drug substance used by the firm is equivalent to and crystal form I, which is used by the innovator product.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks

2557	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Omrax 25mg Tablet Each film coated tablet contains: Omarigliptin….25mg (Antidiabetic)	Form 5D 14-03-2016 PKR 50,000/- (14-03-2016) (**DUPLICATE DOSSIER)**	Malizeb Tablet by MSD (**PMDA Japan** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable level of GMP compliance
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Omrax 25mg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Ruyuan HEC Pharm Co. Ltd, Ruyuan County, Shaoguan City Guandong Province PR China		
API Lot No.	RD201803001		
Description of Pack (Container closure system)	Yellow color round biconvex shape film coated tablet plain from both sides and packed into Alu Alu foil in printed unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD-2463-03-T	18PD-2464-04-T	18PD-2465-05-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Nov-2018	Nov-2018	Nov-2018
Date of Initiation	07-01-2019	07-01-2019	07-01-2019
No. of Batches	03		
Date of Submission	Dy.# 6481 dated 20-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted: • copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated 31-05-2016 • Copy of letter and establishment inspection report by FDA dated 13-11-2015
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 20-04-2018 specifying import of 0.5Kg Omarigliptin along with 20mg impurity A and B each.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

<table>
<tr><th>Shortcoming communicated</th><th>Response received by the firm</th></tr>
<tr><td>Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining the value of “Q” since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. Moreover FDA guidance “Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances” specifies under the heading DISSOLUTION ACCEPTANCE CRITERIA that for immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes.</td><td>Firm has submitted that we have set the dissolution specification NLT 75% as per USFDA and USP.
In all provided stability reports the dissolution results are more than 80% on all intervals and in both conditions which indicates that all results are meeting the USP criteria S1 i.e. Q+5.
Accelerated stability data dissolution results
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<tr><td>18PD-2463-03-T</td><td>93.40</td><td><u>86.60</u></td><td>100.65</td></tr>
<tr><td>18PD-2464-04-T</td><td>95.66</td><td><u>86.88</u></td><td>96.68</td></tr>
<tr><td>18PD-2465-05-T</td><td>90.80</td><td>87.02</td><td><u>85.80</u></td></tr>
</table>
Real time stability data dissolution results
<table>
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<tr><td>18PD-2463-03-T</td><td>93.40</td><td><u>86.53</u></td><td><u>85.17</u></td></tr>
<tr><td>18PD-2464-04-T</td><td>95.66</td><td><u>86.77</u></td><td><u>84.99</u></td></tr>
<tr><td>18PD-2465-05-T</td><td>90.80</td><td>87.05</td><td>97.33</td></tr>
</table>
The exact BCS class of Omarigliptin is not yet identified by PMDA Japan. As per the literature, the solubility of omarigliptin is 543mg/L which makes it an intermediate to high soluble drug. Other gliptins like sitagliptin, vildagliptin, trelagliptin etc are all BCS-III class drugs. As per the USFDA guidelines the value of Q for such drugs should be 80% and for dissolution testing at S-1 level the dissolution limit will become 85% (i.e. Q+5%).
• Out of trend (OOT) results can be seen although all results are still within acceptable criteria / specifications.</td></tr>
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	• **Some results at the borderline of acceptance criteria with 6 months data makes it scientifically difficult to predict the shelf life for 24 months.** • **Since this is a once weekly antidiabetic drug and the drug release from each unit will help to control the glycemic levels for whole week that's why the dissolution results of this particular drug plays very important role.**
Submit the latest GMP certificate of the API manufacturer by the relevant regulatory authority of the country of origin.	Firm has again submitted the same inspection report of FDA dated **13-11-2015** and copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated **31-05-2016**.
Justify the finished product specification without the test for content uniformity.	Firm has submitted that they are not performing content uniformity test on new drug product at initial stage but after getting registration from DRAP after inspection on commercial batches we include the test of content uniformity as per guidelines.
Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	Firm has submitted that they have selected apparatus **2 paddle** method and for rpm the range value of 50 to 75 rpm given we have selected **50 rpm**. Time point for immediate release products in USP BP JP and also FDA is given as 30 miutes so we have adopted this **30 minute** end point for our study. Dissolution medium selection water and dilute hydrochloric acid, buffers in pH range of 1.2 to 7.5 are given. But as omarigliptin is Japanese product son we have considered **0.01N HCl** as dissolution medium. As results founded well within specification we have adopted this dissolution medium. **Firm has not specified the pH of dissolution medium used. Further the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH while the firm has used 0.01N HCl which has pH 2.0.**
Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and solubility	Firm has submitted that the exact crystal form of omarigliptin used in stability batches in Form-V. Firm has also submitted copy of declaration provided by API manufacturer. **The review report / Deliberation result report of the PMDA Japan approved product Marizeb** (http://www.pmda.go.jp/drugs/2015/P20151007002/170050000_22700AMX01014000_A100_2.pdf Accessed on 23-08-2019) **specifies under the heading Quality materials/<Outline of submitted materials>/API/Characteristics as *"The drug substance is recognized in five crystal forms. The production method produces only crystalline form-I (anhydride) which is stable at room temperature"***

Decision of 291st meeting of Registration Board:

Deferred for following:

- Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.
- Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 minutes] with values close to acceptance criteria can be

representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from the reference product [i.e. NLT 75% after 30 minutes].

- Scientific justification of the Out of Trend (OOT) results of dissolution data.
- Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.

Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.

Response by the firm:

1. Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.

Firm has submitted a copy of GMP certificate (No. 2018047) issued by Shaoguan Food and Drug Administration China. The certificate is valid till 04-12-2021.

2. Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from the reference product [i.e. NLT 75% after 30 minutes].

Firm has submitted that that stability study at 9 month interval as per specifications NLT 75% (Q); (Q+5% = 80%) in 30 minutes has been conducted and results were found to be within specifications which is indicative of the pattern for dissolution throughout the shelf-life. The firm has also submitted 9th month long term stability data for Omrax 12.5mg Tablet and Omrax 25mg Tablet.

3. Scientific justification of the Out of Trend (OOT) results of dissolution data.

Firm has submitted that "Dissolution results at 3rd and 6th month interval of stability study data submitted in DRAP were found well within specifications. However, variations observed in Dissolution results were specifically due to the weight variation of tablet for each batch. It may be noted that weight variation of tablets for each batch lies within the defined limits as stated in 978 (2040) Weight Variation USP35 (copy attached) and same can be verified through Assay results for each batch during all stability intervals. (Summary of stability results is enclosed for your easy reference).

Furthermore, we have followed USP for acceptance criteria of dissolution test, which allows to continue dissolution testing till three stages (i.e. S1, S2 & S3) stated in USP General Chapter <711> Dissolution. Therefore, it is evident from dissolution results obtained during stability testing of product are within acceptable limits of S1 stage and declared as normal pattern. However, if in case the results obtained exceed acceptable limit of S1 stage, it is pertinent to note that dissolution testing can be continued till S2 and/or S3 stage as well. If the results then exceed acceptable limits of S2 & S3 stage as well then only it may be considered as OOS which in this case is not relevant as all the results were found within acceptable limits of S1 stage".

4. Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.

Firm has submitted that "We have developed In House method for the dissolution testing of product according to (1092) The Dissolution Procedure: Development and Validation.

Dissolution apparatus 2 paddle method and 50 rpm was selected wherein range value of 50 or 75rpm was mentioned in the reference (copy attached). Time point for immediate release products as stated in USP, BP, JP and US-FDA is 30minutes, therefore we have adopted 30minutes as end point of our study. Water, dilute Hydrochloric Acid and buffers in the pH range of 1.2 to 7.5 were used as dissolution medium.

After a thorough evaluation of solubility of Omarigliptin Tablets, we have considered 0.01N HCl as dissolution medium and same was adopted for dissolution testing parameter in stability studies.

In order to verify solubility profile and release pattern of our product, we have also performed dissolution study in all recommended mediums as mentioned in ICH & EMA and US-FDA guidelines (i.e. pH 1.2, pH 4.5 and pH 6.8). Further, Dissolution Profile study was performed in Buffer pH 2.0 (i.e. 0.01N HCl) as well to justify that there is no significant difference occurring in Buffer pH 2.0 (i.e. 0.01N HCl) & Buffer pH 6.8, which ultimately proves that formulation of Omarigliptin and selected dissolution medium are compatible and accurate".

5. Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.

Firm has submitted that "In the patent of international application published under the Patent Cooperation Treaty (PCT), published date: 2nd March 2017, Patent # WO 2017/032705 A1, it is clearly mentioned that Omarigliptin form-V is more stable.
This patent states that "the known polymorphic forms of Omarigliptin do not seem to be adequately stable under pharmaceutically acceptable conditions and/or tend to convert into each other. Such a conversion of polymorphs often results in an unpredictable behavior of the pharmaceutically active agent with regard to its in-vivo and/or in-vitro properties such as solubility, bioavailability and stability (shelf life)"
It further states ahead "Thus it was an object of the present invention to overcome the drawbacks of the above mentioned prior forms and to provide omarigliptin which is present in a pure and/or stable form. Further, omarigliptin should be provided in a form that can be easily produced also on an industrial scale."
This patent further states in summary "The above objectives are unexpectedly achieved by the provision of a polymorphic form of omarigliptin which is designated omarigliptin form-V"
Conclusion:
This can easily be concluded from above mentioned facts that form-V of Omarigliptin does not have any negative effect on product safety, bioavailability / in-vivo characteristics which may be the risks in other polymorphic forms. Due to this reason we selected this form for generic product development.
Further, comparative study against known omarigliptin crystal form I and V have been performed by API manufacturer M/s Ruyuan HEC Pharm Co. Ltd. and results from the studies proves that "Omarigliptin crystal form V is more stable than the known crystal form I of Omarigliptin, and more suitable for solid preparation application. It is beneficial to improving the bioavailability of the drug, to counteracting the problems of uneven content, purity reduction and the like caused by factors such as time, temperature and humidity".

If agreed, the case may be forwarded for panel inspection and the panel may be requested to verify the following:
The crystal form V of the drug substance used by the firm is equivalent to and crystal form I, which is used by the innovator product.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Omrax (Omarigliptin) 12.5mg and 25mg Tablets by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.1-2/2020-PEC dated 6th July, 2020.
Investigation Date and Time: 02nd July, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:
Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi for registration of Omrax (Omarigliptin) 12.5mg & Omrax (Omarigliptin) 25mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:
1. Prof. Dr. Rafeeq Alam Khan, Dean. Faculty of Pharmacy, Ziauddin University, Karachi (Member Registration Board).
2. Dr. Saif Ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Ms, Sanam Kauser Assistant Director, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Q. No.	Question	Observation by Panel
1.	Do you have documents confirming the import of Omarigliptin API including approval from DRAP?	The firm has imported Omarigliptin 0.5 Kg vide Invoice No. WIS180041 dated April 02, 2018 from M/s WIS Pharmatech Co.Ltd. Manufactured by M/s Ruyuan HEC Pharm Co. Limited for the manufacturing of lab scale batches of Omarigliptin 12.5mg and 25mg Tablets. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the import of Omarigliptin, reference standard and impurity standards?	Firm has documents confirming the import of Omarigliptin, The API working standard and impurities standard were imported at the time of import of the APIs.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, Working standard of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the China, FDA.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method however no degradation products are reported by the manufacturer. Moreover, process related impurities have been quantified during stability studies.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some quantities of the API and working standard, however they have consumed all the impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients which includes Omrax 12.5mg Tablet, microcrystalline cellulose PH.102, Mannitol, Croscarmellose Sodium, Magnesium Stearate. Opadry Yellow II 85G62338 has been used for coating and Omrax 25mg Tablet, microcrystalline cellulose PH.102, Mannitol, Croscarmellose Sodium, Magnesium Stearate. Opadry White 85G68918 has been used for coating.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Omarigliptin 12.5mg and 25mg Tablets?	The firm has written and authorized protocols for the development of Omarigliptin 12.5mg and 25mg Tablets.
15.	Have you performed Drug-	The firm has not performed Drug-excipient Compatibility

	excipient compatibility studies?	studies as the composition of their tablets is similar to that of the innovator product (Marizev Tablets 12.5mg and 25mg manufactured by Takeda, Japan).
16.	Have you performed comparative dissolution studies?	The firm has not performed comparative dissolution profile. As per statement of the firm they could not performed comparative dissolution profile as they were unable to get pack from Japan without Japanese prescription. They however has performed dissolution in three media (pH 1.2, 4.5 and 6.8) and the data shows that the product is highly soluble and dissolves more than 85% within 15minutes in all three media. Firm was required to perform comparative dissolution profile for pharmaceutical equivalency however, keeping in view the high solubility of the product we can predict no significant difference in dissolution rate and extant of the firm product if compared to the innovator product.
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment available in product development section for development of Omarigliptin 12.5mg & 25mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Omarigliptin 12.5mg and 25 mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme/ re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 03 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Omarigliptin 12.5mg and 25mg Tablets as required?	The firm has manufactured three stability batches, each of 2500 tablets, for the stability studies of: Omarigliptin 12.5mg Tablets with Batch Numbers: 18PD-2460-01-T, 18PD-2461-02-T & 18PD-2462-03-T Omarigliptin 25mg Tablets with Batch Numbers: 18PD-2463-03-T, 18PD-2464-04-T & 18PD-2465-05-T The tablets are packed in AluAlu blisters.
23.	Do you have any criteria for fixing the batch size of stability batches?	Batch size has been decided as per requirement the of all the testing stations throughout the shelf life.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation studies.
27.	Do you have method transfer studies in case when the method	Method transfer studies have not been done, however, validation of the method has been performed.

	of testing being used by your firm is given by any other lab?	
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Omarigliptin and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Omarigliptin and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation studies.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show audit trail reports on Omarigliptin testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Accelerated stability studies are over whereas in real time studies 12 months testing has been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Omarigliptin 12.5mg & 25mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Omarigliptin tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.
37.	**Specific Queries by PEC/Board** To verify whether the crystalline form V of the drug substance used by the firm is equivalent to crystalline form I as used by the innovator.	Firm has submitted an international patent publication bearing No. WO2017/032705AI dated 02-03-2017 patented under patent cooperation treaty (PCT) in the name of M/S. Sandoz, AG. Basel, Switzerland, which states that "Form I and Form II are reported to be enantiotropically related and able to convert into each other depending on the temperature. Similarly Form III and Form IV are meta-stable and convert into Form I and II. Such conversion of polymorphs often results in an unpredictable behaviour of the pharmaceutically active agent with regard to its in-vivo and / or in-vitro properties such as solubility, bioavailability and stability. The patent further states that "It was an object of the present invention (Form V) to overcome the drawbacks of the above mentioned prior forms (Form-I-IV) to provide omarigliptin which is present in a pure and / or stable form. The patent further states in the summary that "The above objectives are unexpectedly achieved by the provision of a polymorphic form of omarigliptin which is designated omarigliptin Form-V.

		Keeping in view the above facts and other data presented in patent No. WO2017/032705, Form-V in most stable and highly feasible polymorph to be used in pharmaceutical formulations.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Omrax (Omarigliptin) 12.5mg and 25mg Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Omarigliptin 12.5mg and 25mg Tablets.

Recommendations:
The firm may kindly be granted necessary registration of Omarigliptin 12.5mg and 25mg Tablets**.**

Decision: Registration Board decided to approve registration of Omrax (Omarigliptin) 12.5mg and 25mg Tablets with Innovator's specifications by M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2558.	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.	Silflow Capsule 4mg Each capsule contains: Silodosin …..4mg (Selective alpha 1 adrenergic receptor)	Form 5D Dy No. 8886 27-02-2019 PKR 50,000/- (27-02-2019)	RAPAFLO Capsule (**USFDA** Approved) GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: The case was presented in 291st meeting of Registration Board and was deferred for submission of stability study data.			

STABILITY STUDY DATA

Drug	Silflow Capsule 4mg
Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co. Ltd China
API Lot No.	13000-180501
Description of Pack (Container closure system)	Blue opaque capsule and off white opaque body size "3" properly locked hard gelatin capsule packed in blister pack (2x7's cap) in printed alu-alu foil.
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	SDAT2/18	SDAT3/18	SDAT4/18
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	23-11-2018	23-11-2018	23-11-2018
No. of Batches	03		
Date of Submission	Dy.# 11916 dated 15-07-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of Drug Manufacturing authorization certificate issued by Zhejiang province food and drug administration.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 11-07-2018 specifying import of 0.09Kg silodosin from Zhejiang Tianyu Pharmaceutical Co. Ltd.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30 minutes, since the Clinical Pharmacology & Biopharmaceutics Review specifies that the acceptance criteria for dissolution test is not less than 85% in 15 minutes.	We hereby do agree to adopt dissolution criteria i.e. NLT 85% in 15 minutes and submitting revised Product Test Method (PTM) for your kind information. The results of dissolution test in already submitted stability studies are more than 85% in 15 minutes which complies to observation. **The dissolution testing in already submitted data was conducted at 30 minutes.**
Justify the testing of the product without content uniformity and weight variation test.	Test for uniformity of dosage units by content uniformity (assay method) has been performed as recommended by USP general chapter <905> for both strengths of silodosin 4mg and 8mg. The test has been mentioned in PTM of both strengths. In view of your observation, from day to onward, we will elaborate this test in our PTM according to the application of test "as uniformity of dosage units by content uniformity or weight"

	instead of our existing practice of writing as "meets the requirement of USP 905". Data supporting this study can be verified during on-site inspection.

Decision of 293rd meeting of Registration Board:
Registration Board decided to defer the case and directed the firm to submit dissolution testing data at 15 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:
Firm has submitted stability real time and accelerated study data for 2 Batches SDA-T3-18 and SDA-T4-18 at 0 and 1 month interval in which dissolution acceptance criteria was "NLT 80% Q of labelled amount of silodosin is dissolved in 15 minutes."
The panel may be requested to verify the performance of dissolution test with revised acceptance criteria.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2559.	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.	Silflow Capsule 8mg Each capsule contains: Silodosin …..8mg (Selective alpha 1 adrenergic receptor)	Form 5D Dy No. 8887 27-02-2019 PKR 50,000/- (27-02-2019)	RAPAFLO Capsule (**USFDA** Approved) GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: The case was presented in 291st meeting of Registration Board and was deferred for submission of stability study data.			

STABILITY STUDY DATA

Drug	Silflow Capsule 8mg		
Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.		
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co. Ltd China		
API Lot No.	13000-180501		
Description of Pack (Container closure system)	Dark red opaque cap and off white opaque body size "1" properly locked hard gelatin capsule packed in blister pack (2x7's cap) in printed alu-alu foil.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SDBT2/18	SDBT3/18	SDBT4/18
Batch Size	2000 Capsule	2000 Capsule	2000 Capsule
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	23-11-2018	23-11-2018	23-11-2018
No. of Batches	03		

Date of Submission	Dy.# 11915 dated 15-07-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of Drug Manufacturing authorization certificate issued by Zhejiang province food and drug administration.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 11-07-2018 specifying import of 0.09Kg silodosin from Zhejiang Tianyu Pharmaceutical Co. Ltd.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 70% (Q) in 30 minutes, since the Clinical Pharmacology & Biopharmaceutics Review specifies that the acceptance criteria for dissolution test is not less than 85% in 15 minutes.	We hereby do agree to adopt dissolution criteria i.e. NLT 85% in 15 minutes and submitting revised Product Test Method (PTM) for your kind information. The results of dissolution test in already submitted stability studies are more than 85% in 15 minutes which complies to observation. **The dissolution testing in already submitted data was conducted at 30 minutes.**
Justify the testing of the product without content uniformity and weight variation test.	Test for uniformity of dosage units by content uniformity (assay method) has been performed as recommended by USP general chapter <905> for both strengths of silodosin 4mg and 8mg. The test has been mentioned in PTM of both strengths. In view of your observation, from day to onward, we will elaborate this test in our PTM according to the application of test "as uniformity of dosage units by content uniformity or weight" instead of our existing practice of writing as "meets the requirement of USP 905". Data supporting this study can be verified during on-site inspection.

Decision of 293rd meeting of Registration Board:
Registration Board decided to defer the case and directed the firm to submit dissolution testing data at 15 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Firm has submitted stability real time and accelerated study data for 2 Batches SDB-T3-18 and SDB-T4-18 at 0 and 1 month interval in which dissolution acceptance criteria was "NLT 80% Q of labelled amount of silodosin is dissolved in 15 minutes."
The panel may be requested to verify the performance of dissolution test with revised acceptance criteria.

INSPECTION REPORT

1.1 General Information

Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt.) Ltd.
Physical Address	62 Industrial Estate, Kot Lakhpat, Lahore.
Drug Manufacturing License No. and validity	000052 by way of formulation Valid till 20-07-2020.
Contact Address	Irfan Sohail Senior Manager Regulatory Affairs 0308-8884984
Date of Inspection	2nd – 3rd July, 2020
Purpose of Inspection	Verification of authenticity of stability data for purpose of registration of drugs with reference DRAP's letter no. F.1-2/2020-PEC dated 22-04-2020.
Name of Inspector	01. Dr. Muzammal Waheed Director, DTL, Faisalabad. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Hafiz Ahsan Assistant Director, DRAP, Islamabad.
Name of firm Representatives	• Dr. Rizwan Mahmood Director Quality Operations • Irfan Sohail Senior Manager Regulatory Affairs • Shahid Anwar General Manager R&D • Farhan Qureshi GM Quality Assurance • Muhammad Fiaz Quality Control Manager

1.2 General Information about unit:

M/s. CCL is a private limited company and was licensed in the year 1976, initially and shifted to the existing site in 1984. The firm has production facility, supply chain, engineering, quality control, quality assurance, research & development, regulatory and administrative departments. The production operations at firm involve manufacturing, packaging and distribution of finished pharmaceutical products. The firm is manufacturing generic products and involved in export to various countries.

1.3 Focus of Inspection:

The inspection was focused on a thorough evaluation of data for stability studies of following products namely:

Sr. No.	Name / Composition of Drugs
01	Silflow Capsule 4mg Each capsule contains: Silodosin……..…4mg
02	Silflow Capsule 8mg

	Each capsule contains: Silodosin……..…8mg

Details of investigation:

Q. No.	Contents	Remarks
1.	Do you have documents confirming the import of Silodosin including approval from DRAP?	The firm has imported Silodosin raw material vide invoice no. TYI18426 dated 02-07-2018 from M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. China and got DRAP approval vide no. 9371/2018/DRAP dated 11-07-2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm selected M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd., China for Silodosin based on their vendor evaluation mechanism.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Silodosin working standard and impurity standard (YDL 11) from API supplier dated 02-09-2018.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm had certificates of analysis for API, working standard and impurity standard.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has valid GMP Certificate of M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd., China valid till 28-03-2022.
6.	Do you use API manufacturer method of testing for testing APIs?	The firm used API manufacturer's method of testing for API testing. *During inspection, it was also brought into the notice of the firm that Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Moreover, the firm was advised to develop method transfer protocol for testing APIs.*
7.	Do you have stability studies reports on APIs?	The firm had stability studies reports on API of API manufacturer. Accelerated ($40^oC \pm 2^oC$ / RH75% ± 5%) – 6 months Real time ($30^oC \pm 2^oC$ / RH75% ± 5%) – 24 months
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer has performed stability as per SIM method and impurities (YDL-11, YDL-Imp-1, YDL-Imp-2, YDL-Imp-3, YDL-Imp-4) has been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has testing method to quantify the impurity (YDL-11) as provided by API manufacturer.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has no remaining quantities of the working standard and impurity standard.
11.	Have you used pharmaceutical grade excipients?	The firm used pharmaceutical grade excipients including Mannitol-D, Pre-Gelatinized starch, Sodium lauryl sulphate, Magnesium stearate, E.H.G shell size "1" (Cap: Dark red opaque; Body: Off-white opaque) and E.H.G shell size "3" (Cap: Dark blue opaque; Body: Off-white opaque)
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has certificates of analysis of the excipients used.

<table>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of Silodosin Capsule 4mg and Silodosin Capsule 8mg?</td><td>The firm has written and authorized protocols for the development of Silodosin Capsule 4mg and Silodosin Capsule 8mg.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipient compatibility studies?</td><td>The firm has performed drug-excipient compatibility studies under stress conditions of 60°C ± 2°C / 75% ± 5% RH.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies for Silodosin Capsule 8mg with Rapaflo Capsule 8mg, manufactured by M/s. Balkan Pharma, USA using paddle apparatus at 50rpm in 900ml of the following dissolution mediums:
10. HCl buffer
11. Acetate buffer
12. Phosphate buffer</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Silodosin Capsule 4mg and Silodosin Capsule 8mg?</td><td>The firm has used commercial production area for filling of capsules using semi-automatic capsule filling machine. The log books of equipment also confirm the filling of capsules in respective dates.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section were qualified however, the firm was advised to perform qualifications of equipment from authorized bodies.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Yes.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Silodosin Capsule 4mg and Silodosin Capsule 8mg as required?</td><td>The firm had manufactured three initial stability batches for the stability studies of Silodosin Capsule 4mg with batch numbers i.e. SDA-T2/18, SDA-T3/18 and SDA-T4/18 and of Silodosin Capsule 8mg with batch numbers i.e. SDB-T2/18, SDB-T3/18 and SDB-T4/18. The accelerated studies were done in Climatic test chamber (Model: HPP-749; Making Memmert, Germany) and long-term studies were done in Climatic test chamber (Model: HPP-750, Making Memmert, Germany).
Samples were taken from stability chamber and tested at 0, 1, 3 months at accelerated and real time conditions with revised dissolution specifications.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm had followed in-house SOP for fixing the batch size of stability batches.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of stability batches.
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td colspan="3">Silodosin Capsule 4mg</td></tr>
<tr><td>SDA-T2-18</td><td>2,000</td><td>11-2018</td></tr>
<tr><td>SDA-T3-18</td><td>2,000</td><td>11-2018</td></tr>
<tr><td>SDA-T4-18</td><td>2,000</td><td>11-2018</td></tr>
<tr><td colspan="3">Silodosin Capsule 8mg</td></tr>
<tr><td>SDB-T2-18</td><td>2,000</td><td>11-2018</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td><table>
<tr><td>SDB-T3-18</td><td>2,000</td><td>11-2018</td></tr>
<tr><td>SDB-T4-18</td><td>2,000</td><td>11-2018</td></tr>
</table></td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has protocols for testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had developed and validated the assay method for testing of stability batches of applied formulations.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Silodosin API and the finished drug?</td><td>The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Silodosin API and the finished drug. However, the firm was advised to qualify the equipments / instruments from authorized bodies.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm has conducted stress testing of finished product.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>API testing, FPP testing and compatibility testing has been conducted on HPLCs which were not 21 CFR compliant. However, the firm has procured 21 CFR part 11 compliant HPLC.</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports on Silodosin Capsule 4mg and Silodosin Capsule 8mg testing?</td><td>Initially, audit trail was not enabled. However, log of data was available on the HPLCs. The data was also checked through hard copies of chromatograms.
However in revised FPP testing, audit trail was enabled.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches kept on stability testing:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Capsules used for stability studies</th><th>Remaining Quantity (Stability)</th></tr>
<tr><td colspan="4">Silodosin 4mg Capsules</td></tr>
<tr><td>SDA-T2-18</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>SDA-T3-18</td><td>2,000</td><td>540</td><td>144</td></tr>
<tr><td>SDA-T4-18</td><td>2,000</td><td>540</td><td>144</td></tr>
<tr><td colspan="4">Silodosin 8mg Capsules</td></tr>
<tr><td>SDB-T2-18</td><td>2,000</td><td>324</td><td>72</td></tr>
<tr><td>SDB-T3-18</td><td>2,000</td><td>540</td><td>144</td></tr>
<tr><td>SDB-T4-18</td><td>2,000</td><td>540</td><td>144</td></tr>
</table></td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has stability batches kept on stability testing.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipment used in Silodosin Capsule 4mg and Silodosin Capsule 8mg production and analysis?</td><td>The firm has valid calibration status for the equipment used in Silodosin Capsule 4mg and Silodosin Capsule 8mg production and analysis.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Adequate monitoring and control was available for stability chamber. The firm was advised to improve alarm system.</td></tr>
</table>

36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Requisite facilities are satisfactory and GMP compliant (DRAP ref. no. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 valid for 3 years).

VERIFICATION:

(i) The firm performed dissolution test in the presence of panel as per revised dissolution acceptance criteria on SDA-T2/18 of Silodosin Capsule 4mg at dissolution apparatus (Pharma Test DT-70) and analysis was done at 21 CFR compliant HPLC Agilent QC # 122. The results were within dissolution acceptance limit i.e., NLT 80% Q in 15 minutes (copy of raw data sheet attached).

(ii) The firm had revised the dissolution limits i.e., NLT 80% Q in 15 minutes in Product Test Method.

CONCLUSIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. CCL Pharmaceuticals (Pvt.) Ltd., at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan have conducted stability studies of the following products: **However few points are being recorded for the kind perusal of the Drug Registration Board, against questions 6, 19, 28, 30, 31 and 35 of the check list.**

Sr. No.	Name / Composition of Drugs
01	Silflow Capsule 4mg Each capsule contains: Silodosin……..…4mg
02	Silflow Capsule 8mg Each capsule contains: Silodosin……..…8mg

Decision: Registration Board decided to approve registration of Silflow (Silodosin) 4mg and 8mg capsule with Innovator's specifications by M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2560	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.	Vemteno Tablet 25mg Each film coated tablet contains: Tenofovir alfenamide (as fumarate) ….25mg (Anti-viral)	Form 5 27-02-2019 PKR 20,000/- (27-02-2019)	Vemlidy Tablet by Gilead Sciences (**USFDA** Approved) GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			
	STABILITY STUDY DATA			

Drug	Vemteno Tablet 25mg		
Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.		
Manufacturer of API	Cipla Ltd. at plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune Mahrashtra India		
API Lot No.	LDP170006		
Description of Pack (Container closure system)	Pink round biconvex shape film coated tablet packed in Alu-Alu in bleach board with leaflet		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T2/17	T3/17	T4/17
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2017	08-2017	07-2017
Date of Initiation	08-2017	08-2017	08-2017
No. of Batches	03		
Date of Submission	Dy.# 7194 dated 25-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Government of Karnataka, Drugs Control Department dated 21-02-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 24-02-2017 specifying import of 0.21Kg tenofovir alafenamide fumarate. The exact manufacturing site of the API manufacturer is not mentioned in the submitted invoice.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[3]

Shortcomings	Response by the firm

<table>
<tr>
<td>Justify the acceptance criteria of dissolution test i.e. NLT 70% Q after 30 minutes since the value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading DISSOLUTION ACCEPTANCE CRITERIA that for immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes. Furthermore, USFDA chemistry review for the innovator product "Vemlidy Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 15 minutes.</td>
<td>Firm has submitted that as per CDP performed their results show more than 85% release in 15 minutes in Acetate Buffer pH 4.5.
Initially we have used parameters taken from USFDA dissolution methods but after your good self highlighted the document of chemistry review, which suggests sampling time of 15 minutes. It is acknowledge & commit to revise product test method with revised sampling time and Q value which can be verified during on-site inspection.

<table>
<tr><th>Dissolution Specifications of the firm</th><th>Dissolution Specifications of innovator product</th></tr>
<tr><td>NLT 70% (Q) after 30 minutes</td><td>NLT 80%(Q) after 15 minutes</td></tr>
</table>

Firm has performed complete stability studies as per the specification which is different from innovator product. Further the dissolution testing during CDP studies or at 9th month interval cannot be used to predict the product quality profile in terms of dissolution studies during 6 months accelerated study as well as during real time studies.</td>
</tr>
<tr>
<td>Specify the exact storage conditions at which the API was kept after ADC clearance in February 2017 till the manufacturing of batches in July and August 2017.</td>
<td>Firm has submitted that they have kept the material at 2-8 degree which is the recommended storage condition for this drug.</td>
</tr>
<tr>
<td>The submitted GMP certificate is of Cipla Limited Old Madras Road Virgonagar Post Bangalore (No. NB-110/78), while as per certificate of analysis the manufacturing site of API is Cipla Ltd. Plot D-22, MIDC Industrial Area, Kurkumbh Village, Taluka – Daund, District Pune, Mahrashtra. Clarify the exact manufacturing site and submit the GMP certificate.</td>
<td>Firm has submitted that the exact manufacturing site is Cipla Ltd. at plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune Mahrashtra India. The GMP certificate of said site can be verified during on-site inspection.
The firm has not submitted GMP certificate of the API manufacturer.</td>
</tr>
</table>

Firm has performed 3rd month testing of batch T4-17 on 16-11-2017 which is 15 days earlier than 3 months period. Firm has submitted that as per their protocols they can test the product within 1 month of due date.

Decision of 292nd meeting of Registration Board:

Deferred for following:

- Scientific justification how the CDP studies or stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 80% (Q) in 15 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from innovator product [i.e. NLT 70% (Q) after 30 minutes].
- Submission of valid GMP certificate from API manufacturer.

Response of the firm:

Firm has submitted that:

- We have developed our product in 07-2017 and adopted dissolution test method as per USFDA established on 19—01-2017. As highlighted by your office, the chemistry review was updated on 27-11-2017, therefore it was not incorporated in initial studies.
- Firm has submitted copy of GMP certificate of Cipla Ltd. plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune Mahrashtra India, issued by FDA Mahrashtra dated 13-11-2018

Decision of 293rd meeting of Registration Board:

Registration Board decided to defer the case and directed the firm to submit dissolution testing data at 15 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:
Firm has submitted stability real time and accelerated study data for following 2 new Batches at 0 and 1 month interval in which dissolution acceptance criteria was "NLT 80% Q of labelled amount of tenofovir alafenamide is dissolved in 15 minutes."
1. T5-20 (Mfg date: 01-2020, testing date: 02-2020: Batch size 600 tablet)
2. T6-20 (Mfg date: 01-2020, testing date: 02-2020: Batch size 600 tablet)

The panel may be requested to verify the development of two new batches and performance of dissolution test with revised acceptance criteria.

INSPECTION REPORT

1.4 General Information

Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt.) Ltd.
Physical Address	62 Industrial Estate, Kot Lakhpat, Lahore.
Drug Manufacturing License No. and validity	000052 by way of formulation Valid till 20-07-2020.
Contact Address	Irfan Sohail Senior Manager Regulatory Affairs 0308-8884984
Date of Inspection	2nd – 3rd July, 2020
Purpose of Inspection	Verification of authenticity of stability data for purpose of registration of drugs with reference DRAP's letter no. F.1-2/2020-PEC dated 22-04-2020.
Name of Inspector	01. Dr. Muzammal Waheed Director, DTL, Faisalabad. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Hafiz Ahsan Assistant Director, DRAP, Islamabad.
Name of firm Representatives	• Dr. Rizwan Mahmood Director Quality Operations • Irfan Sohail Senior Manager Regulatory Affairs • Shahid Anwar General Manager R&D • Farhan Qureshi GM Quality Assurance • Muhammad Fiaz Quality Control Manager

1.5 General Information about unit:

M/s. CCL is a private limited company and was licensed in the year 1976, initially and shifted to the existing site in 1984. The firm has production facility, supply chain, engineering, quality control, quality assurance, research & development, regulatory and administrative departments. The production operations at firm involve manufacturing, packaging and distribution of finished pharmaceutical products. The firm is manufacturing generic products and involved in export to various countries.

1.6 Focus of Inspection:

The inspection was focused on a thorough evaluation of data for stability studies of following product namely:

Sr. No.	Name / Composition of Drugs
01	Vemteno Tablet 25mg Each film coated tablet contains:

	Tenofovir alafenamide (as fumarate)……25mg

Detail of investigation:

Q. No.	Contents	Remarks
1.	Do you have documents confirming the import of Tenofovir alafenamide fumarate including approval from DRAP?	The firm has imported Tenofovir alafenamide fumarate raw material vide invoice no. 6001322169 dated 07-02-2017 from M/s. Cipla Ltd., India and got DRAP approval vide no. 2723/2017/DRAP dated 24-02-2017.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm selected M/s Cipla Ltd., India based on their vendor evaluation mechanism.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Tenofovir alafenamide fumarate working standard and impurities standards [9-(2-Phosphonyl Methoxy Propyl) Adenine (PMPA)] & Ten phenol from API supplier dated 24-02-2017.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm had certificates of analysis for API, working standard and impurities standards for impurities.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm had valid GMP Certificate of M/s. Cipla Ltd., India issued by Food & Drugs Administration, Maharashtra, India valid till 07-11-2021.
6.	Do you use API manufacturer method of testing for testing API?	*The firm has partially adopted API manufacturer's method of testing. Moreover, the firm was advised to develop method transfer protocol for testing APIs.*
7.	Do you have stability studies reports on API?	The firm has stability studies reports of API from API manufacturer: Accelerated (25^{o}C±2^{o}C/RH60% ±5%)-6 months Real time (2^{o}C - 8^{o}C) – 18 months
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The API manufacturer has performed stability as per SIM method and impurities (PMPA, Ten phenol), Fumaric acid, Enantiomeric purity (D-Alanine isomer 1, D-Alanine isomer 2, L-Alanine isomer 1) has been quantified.
9.	Do you have method for quantifying the impurities in the API?	*The firm had testing method to quantify the impurities (PMPA & Ten phenol) as provided by API manufacturer. The firm did not perform Fumaric acid contents and Enantiomeric purity and relied on the results of API manufacturer However, the firm undertake that upon commercial manufacturing, they will perform said tests and results will be submitted to DRAP.*
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had no remaining quantities of the working standard and impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm had used pharmaceutical grade excipients including Avicel pH 102, Lactose Monohydrate, Croscarmellose sodium, Magnesium stearate, Opadry pink 200F240014 and Opadry clear OY-S-29019.
12.	Do you have documents confirming the import of the used excipients?	The firm had necessary documents confirming the import of the used excipients.

13.	Do you have test reports and other records on the excipients used?	The firm had certificates of analysis of the excipients used.
14.	Do you have written and authorized protocols for the development of Tenofovir alafenamide fumarate Tablets?	The firm has written and authorized protocols for the development of Vemteno Tablet 25mg.
15.	Have you performed Drug-excipient compatibility studies?	The firm has performed drug-excipient compatibility studies under stress conditions of 60°C ± 2°C / 75% ± 5% RH.
16.	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Vemteno Tablet 25mg with Vemlidy Tablet 25mg, manufactured by M/s. Gilead Sciences, Inc. USA using paddle apparatus at 75rpm in 500ml of the following dissolution mediums: 13. HCl buffer 14. Acetate buffer 15. Phosphate buffer
17.	Do you have product development (R&D) section	The firm had product development (R&D) section.
18.	Do you have necessary equipment available in product development section for development of Tenofovir alafenamide fumarate Tablets?	Product development section has necessary equipment to develop Vemteno Tablets 25mg.
19.	Are the equipment in product development section qualified?	The available equipment in product development section were qualified *however, the firm was advised to perform qualifications of equipment from authorized bodies.*
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes.
22.	Have you manufactured three stability batches for the stability studies of Tenofovir alafenamide fumarate Tablets as required?	The firm had manufactured three initial stability batches for the stability studies of Vemteno Tablets 25mg with batch numbers i.e. T2-17, T3-17, T4-17 and later-on two more stability batches T5-20, T6-20 were manufactured. The accelerated studies were done in Climatic test chamber (Model: HPP-749; Making Memmert, Germany) and long-term studies were done in Climatic test chamber (Model: HPP-750, Making Memmert, Germany). *The firm has manufactured two new trial batches of formulation and tested at 0,1,3 months accelerated and real time stability conditions and also revised dissolution limits as per reference formulations.*
23.	Do you have any criteria for fixing the batch size of stability batches?	The firm had followed in-house SOP for fixing the batch size of stability batches.

<table>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm had record of production of stability batches:

<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>T2-17</td><td>1,500</td><td>07-2017</td></tr><tr><td>T3-17</td><td>1,500</td><td>08-2017</td></tr><tr><td>T4-17</td><td>1,500</td><td>08-2017</td></tr><tr><td>T5-20</td><td>600</td><td>01-2020</td></tr><tr><td>T6-20</td><td>600</td><td>01-2020</td></tr></table></td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm had protocol for stability testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had developed method of Vemteno Tablet 25mg (RD-PTM-05 B) and validated the test method (CCL-AMVR-212) for testing of stability batches.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir alafenamide fumarate API and the finished drug?</td><td>The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of tenofovir alafenamide fumarate API and the finished product. However, the firm was advised to qualify the equipments / instruments from authorized bodies.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm had conducted stress testing of finished product.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>API testing, FPP testing and compatibility testing has been conducted on HPLCs which were not 21 CFR compliant.
However, the firm has procured 21 CFR part 11 compliant HPLC.</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports on Tenofovir alafenamide fumarate testing?</td><td>Initially, audit trail was not enabled. However, log of data was available on the HPLCs. The data was also checked through hard copies of chromatograms.
However in revised FPP testing, audit trail was enabled.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches kept on stability testing:

<table><tr><th>Batch No</th><th>Batch size</th><th>Tablets used for stability studies</th><th>Remaining Quantity (Stability)</th></tr><tr><td>T2-17</td><td>1,500</td><td>324</td><td>36</td></tr><tr><td>T3-17</td><td>1,500</td><td>324</td><td>36</td></tr><tr><td>T4-17</td><td>1,500</td><td>324</td><td>36</td></tr><tr><td>T5-20</td><td>600</td><td>216</td><td>72</td></tr><tr><td>T6-20</td><td>600</td><td>216</td><td>72</td></tr></table></td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has stability batches kept on stability testing.</td></tr>
</table>

34.	Do you have valid calibration status for the equipment used in Tenofovir alafenamide fumarate tablets production and analysis?	The firm has valid calibration status for the equipment used in Vemteno Tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control was available for stability chamber. *The firm was advised to improve alarm system.*
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Requisite facilities are satisfactory and GMP compliant (DRAP ref. no. 118/2019-DRAP (AD-789112-762) dated 13-05-2019 valid for 3 years).

VERIFICATION:

(i) The firm performed dissolution test in the presence of panel as per revised dissolution acceptance criteria on T5-20 of Vemteno Tablet 25mg at dissolution apparatus (Agilent 708-DS) and analysis was done at 21 CFR compliant HPLC Agilent RD # 034. The results were within stipulated limits (copy of raw data sheet attached).

(ii) The firm had revised the dissolution limits i.e., NLT 80% Q in 15 minutes in Product Test Method.

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. CCL Pharmaceuticals (Pvt.) Ltd., at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan has conducted stability studies of the following product: However few points are being recorded for the kind perusal of the Drug Registration Board, against questions 6, 9, 19, 28, 30, 31 and 35 of the check list.

Sr. No.	Name / Composition of Drugs
01	Vemteno Tablet 25mg Each film coated tablet contains: Tenofovir alafenamide (as fumarate)……25mg

Decision: Registration Board decided to approve registration of Vemteno (Tenofovir alafenamide (as fumarate)) 25mg tablet with Innovator's specifications by M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data

i. New cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
2561	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empaz 10mg Tablet Each Film Coated Tablet Contains: Empagliflozin……10mg	Form-5D Dy.No.2030 03-04-2017 Fee. 50,000/-	Jardiance Tablets (**USFDA** Approved)

2562.	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empaz 25mg Tablet Each Film Coated Tablet Contains: Empagliflozin……25mg	Form-5D Dy.No.2031 03-04-2017 Fee. 50,000/-	GMP certificate issued on the basis of inspection conducted dated 08-11-2018.

STABILITY STUDY DATA			
Manufacturer of API	Century Pharmaceuticals Limited, 103-106, GIDC, Halol, 389 350, Dist Panchmahal		
API Lot No.	08855002-EMP		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
EMPAZ 10MG TABLET			
Batch No.	RD-19008	RD-19009	RD-19010
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	06-03-2019	06-03-2019	06-03-2019
EMPAZ 25MG TABLET			
Batch No.	RD-19012	RD-19013	RD-19020
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	06-03-2019	06-03-2019	06-03-2019
No. of Batches	03		
Date of submission	30389 (15-01-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.20041958) issued by Food & Drug Control Administration, Gujrat State India. It is valid until 29/03/2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for

		manufacturing of empazmet and empazmet XR tablets.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.		Yes
Commitment to continue real time stability study till assigned shelf life of the product.		Yes
Commitment to follow Drug Specification Rules, 1978.		Yes
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Daplozmet Tablet 5mg/1000mg and Daplozmet Tablet 5mg/850mg (Dapagliflozin propanediol monohydrate + metformin HCl) Tablets", which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of Daplozmet Tablet. Date of inspection: 1st January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for manufacturing of empazmet and empazmet XR tablets.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.20041958) issued by Food & Drug Control Administration, Gujrat State India. It is valid until 29/03/2022.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted protocols / SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: **EMPAZ 10MG TABLET**

		RD-19008: 228 Tablets RD-19009: 228 Tablets RD-19010: 228 Tablets **EMPAZ 10MG TABLET** RD-19012: 228 Tablets RD-19013: 228 Tablets RD-19020: 228 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches of both API's.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted results of compatibility study report of empagliflozin API with all the excipients using binary mixtures and study of compatibility using HPLC analysis.
18.	Record of comparative dissolution data.	Firm has submitted CDP data with of innovator product the f2 values at all three dissolution medium was more than 50.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Evidence of import of API including copy of commercial invoice signed by AD (I&E) DRAP Lahore.	Firm has submitted copy of commercial invoice specifying import of 50Kg empagliflozin. The invoice is cleared by AD (I&E) DRAP Lahore dated 28-01-2020. The invoice is freshly cleared while batches were manufactured in March 2019.
Justify why the content uniformity test is not performed.	Firm has submitted that they have performed content uniformity test only at initial stage. They have also submitted the results of content uniformity at initial time point.
Justify why the testing at different time points is carried out using different HPLC equipment i.e. Agilent Technologies and Schimadzu Lab solutions.	The stability at all time points was performed using 21 CFR compliant system. Depending upon the availability of system different HPLC equipment were used.
Justify the dissolution specification NLT 80%(Q) after 30 minutes, since the USFDA review document of the innovator product specify dissolution specifications i.e. NLT (Q) after 15 minutes. Submit the data of dissolution testing at 15 minutes time point at initial and one-month time point at both accelerated and real time stability conditions for 2	Firm has performed dissolution testing of all the three batches at 15 minutes time point at initial and 1 month time point as per the guidelines of Registration Board and have submitted the results. All results at 15 minutes time point fall within the acceptable limit.

batches as per the decision of 293rd meeting of Registration Board.	

Decision: Registration Board decided to approve registration of Empaz (Empagliflozin) 10mg and 25mg Tablet with Innovator's specifications by M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
2563	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet 5/500 mg Tablet Each Film Coated Tablet Contains: Empagliflozin … 5mg Metformin HCl …500mg	Dy No.3072 Dated.13.04.2017 Rs.50000	Jardiance Tablets (**USFDA** Approved) GMP certificate issued on the basis of inspection conducted dated 08-11-2018.
2564	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet 12.5/500 mg Tablet Each Film Coated Tablet Contains: Empagliflozin … 12.5mg Metformin HCl …500mg	Dated.13.04.2017 Rs.50000	
2565	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet 5/1000 mg Tablet Each Film Coated Tablet Contains: Empagliflozin … 5mg Metformin HCl …1000mg	Dy No.3069 Dated.13.04.2017 Rs.50000	
2566	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet 12.5/1000 mg Tablet Each Film Coated Tablet Contains: Empagliflozin … 12.5mg Metformin HCl …1000mg	50,000/- R&I dy No.3071 Dated:-13.04.2017	

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Century Pharmaceuticals Limited 103 – 106 GIDC, Halol, 389 350 District Panchmahal Gujrat Estate India. **Metformin:** IPCA Laboratories Limited. H-4 MIDC, Waluj Aurangabad 431136 Mahrashtra State India.		
API Lot No.	**Empagliflozin:** 08855002-EMP **Metformin:** 19010 ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
EMPAZMET 5/500 MG TABLET			
Batch No.	RD-19067	RD-19068	RD-19069
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets

Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	05-2019	05-2019	05-2019
EMPAZMET 12.5/500 MG TABLET			
Batch No.	RD-19070	RD-19071	RD-19072
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	05-2019	05-2019	05-2019
EMPAZMET 5/1000 MG TABLET			
Batch No.	RD-19061	RD-19062	RD-19063
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	05-2019	05-2019	05-2019
EMPAZMET 12.5/1000 MG TABLET			
Batch No.	RD-19064	RD-19065	RD-19066
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	04-2019	04-2019	04-2019
Date of Initiation	05-2019	05-2019	05-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate (No. 20011803) issued by Food And Drugs Control Administration Gujrat Estate India. The certificate is valid till 08-01-2023. **Metformin:** Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Mahrashtra. The certificate is valid till 27-08-2021.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Empagliflozin:** Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for manufacturing of empazmet and empazmet XR tablets. **Metformin:** Firm has submitted copy of commercial invoice specifying import of 3000 Kg metformin dated 27-11-2018. The invoice is signed by AD (I&E) DRAP Lahore.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data /	Yes

documents.		
Commitment to continue real time stability study till assigned shelf life of the product.		Yes
Commitment to follow Drug Specification Rules, 1978.		Yes
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Daplozmet Tablet 5mg/1000mg and Daplozmet Tablet 5mg/850mg (Dapagliflozin propanediol monohydrate + metformin HCl) Tablets", which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of Daplozmet Tablet. Date of inspection: 1st January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for manufacturing of empazmet and empazmet XR tablets. **Metformin:** Firm has submitted copy of commercial invoice specifying import of 3000 Kg metformin dated 27-11-2018. The invoice is signed by AD (I&E) DRAP Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate (No. 20011803) issued by Food And Drugs Control Administration Gujrat Estate India. The certificate is valid till 08-01-2023. **Metformin:** Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Mahrashtra. The certificate is valid till 27-08-2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		

9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted protocols / SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided the remaining quantities of the product for each batch.
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	**Empagliflozin:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 75±5%RH) stability studies reports of three batches for 36 month. **Metformin:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches for 60 month.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted results of compatibility study report of both API with all the excipients using binary mixtures and study of compatibility using HPLC analysis.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of all strengths of their product against the innovator product.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC[3]:

Decision: Registration Board decided to approve registration of following drugs with Innovator's specifications by M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore.

- **Empazmet 5/500 mg Tablet**
- **Empazmet 12.5/500 mg Tablet**
- **Empazmet 5/1000 mg Tablet**
- **Empazmet 12.5/1000 mg Tablet**

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
2567	M/s Highnoon Laboratories Limited	Empazmet XR 5/1000 mg Tablet Each Film Coated Tablet Contains:	Form-5D Dy.No 29614 dated 04-09-2018 Rs.50,000/-	Jardiance XR Tablets (**USFDA**

	17.5 K. M. Multan Road, Lahore	Empagliflozin (as immediate release layer)… 5mg Metformin HCl (as extended release layer)…1000mg	Dated 04-09-2018	Approved) GMP certificate issued on the basis of inspection conducted dated 08-11-2018.
2568	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet XR 10/1000 mg Tablet Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 10mg Metformin HCl (as extended release layer)…1000mg	Form-5D Dy.No 29615 dated 04-09-2018 Rs.50,000/- Dated 04-09-2018	
2569	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet XR 12.5/1000 mg Tablet Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 12.5mg Metformin HCl (as extended release layer)…1000mg	Form-5D Dy.No 29617 dated 04-09-2018 Rs.50,000/- Dated 04-09-2018	
2570	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Empazmet XR 25/1000 mg Tablet Each Film Coated Tablet Contains: Empagliflozin (as immediate release layer)… 25mg Metformin HCl (as extended release layer)…1000mg	Form-5D Dy.No 29616 dated 04-09-2018 Rs.50,000/- Dated 04-09-2018	

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Century Pharmaceuticals Limited 103 – 106 GIDC, Halol, 389 350 District Panchmahal Gujrat Estate India. **Metformin:** IPCA Laboratories Limited. H-4 MIDC, Waluj Aurangabad 431136 Mahrashtra State India.
API Lot No.	**Empagliflozin:** 08855002-EMP **Metformin:** 19010 ML2AJMI
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)

EMPAZMET XR 5/1000 MG TABLET

Batch No.	RD-19082	RD-19083	RD-19084
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	06-2019	06-2019	06-2019

EMPAZMET XR 10/1000 MG TABLET

Batch No.	RD-19085	RD-19086	RD-19087
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2019	05-2019	05-2019

Date of Initiation	06-2019	06-2019	06-2019
EMPAZMET XR 12.5/1000 MG TABLET			
Batch No.	RD-19088	RD-19089	RD-19090
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	06-2019	06-2019	06-2019
EMPAZMET XR 25/1000 MG TABLET			
Batch No.	RD-19091	RD-19092	RD-19093
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	06-2019	06-2019	06-2019
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Documents To Be Provided		**Status**	
COA of API		Yes	
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.		**Empagliflozin:** Firm has submitted copy of GMP certificate (No. 20011803) issued by Food And Drugs Control Administration Gujrat Estate India. The certificate is valid till 08-01-2023. **Metformin:** Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Mahrashtra. The certificate is valid till 27-08-2021.	
Protocols followed for conduction of stability study and details of tests.		Yes	
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.		Yes	
Documents confirming import of API etc.		**Empagliflozin:** Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for manufacturing of empazmet and empazmet XR tablets. **Metformin:** Firm has submitted copy of commercial invoice specifying import of 3000 Kg metformin dated 27-11-2018. The invoice is signed by AD (I&E) DRAP Lahore.	
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.		Yes	
Commitment to continue real time stability study till assigned shelf life of the product.		Yes	
Commitment to follow Drug Specification Rules, 1978.		Yes	
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA			

ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Daplozmet Tablet 5mg/1000mg and Daplozmet Tablet 5mg/850mg (Dapagliflozin propanediol monohydrate + metformin HCl) Tablets", which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of Daplozmet Tablet. Date of inspection: 1st January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of Form 3, commercial invoice dated 25-09-2018 specifying import of 6Kg Empagliflozin. The invoice is not signed by AD (I&E) DRAP Lahore, but the firm has submitted copy of letter for permission to import empagliflozin for manufacturing of empazmet and empazmet XR tablets. **Metformin:** Firm has submitted copy of commercial invoice specifying import of 3000 Kg metformin dated 27-11-2018. The invoice is signed by AD (I&E) DRAP Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate (No. 20011803) issued by Food And Drugs Control Administration Gujrat Estate India. The certificate is valid till 08-01-2023. **Metformin:** Firm has submitted copy of GMP certificate (No. 67318/2018/11/24741) issued by FDA Mahrashtra. The certificate is valid till 27-08-2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted protocols / SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength. Firm has manufactured the batches using empagliflozin in coating solution exactly as per the reference product.

11.	Record of remaining quantities of stability batches.	Firm has provided the remaining quantities of the product for each batch.
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	**Empagliflozin:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 75±5%RH) stability studies reports of three batches for 36 month. **Metformin:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches for 60 month.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted results of compatibility study report of both API with all the excipients using binary mixtures and study of compatibility using HPLC analysis.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of all strengths of their product against the innovator product.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC[3]:

Decision: Registration Board decided to approve registration of following drugs with Innovator's specifications by M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore.

- **Empazmet XR 5/1000 mg Tablet**
- **Empazmet XR 10/1000 mg Tablet**
- **Empazmet XR 12.5/1000 mg Tablet**
- **Empazmet XR 25/1000 mg Tablet**

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
2571	Getz Pharma (Pvt) Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Lesiget Tablets 200mg Each film coated tablet contains:- Lesinurad……. 200mg (Anti gout preparation)	Form 5D Dy No. 3077 31-01-2017 PKR 50,000/- 31-01-2017	Zurampic Tablets (**USFDA** Approved but **<u>Discontinued</u>**) 01-07-2019: acceptable level of compliance of GMP requirements.
STABILITY STUDY DATA				

Drug	Lesiget Tablets 200mg		
Name of Manufacturer	M/s Getz Pharma (Pvt) Ltd. 29-30/27, Korangi Industrial Area, Karachi.		
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., LTD, China		
API Lot No.	20180812		
Description of Pack (Container closure system)	Light pink colored, oblong shaped, biconvex film coated tablet, plain on both sides packed in Alu-PVDC blister, further packed in secondary carton.		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 1, 3, 4, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	442DS01	442DS02	442DS03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	07-2018	08-2018	08-2018
Date of Initiation	16-08-2018	16-08-2018	16-08-2018
No. of Batches	03		
Date of Submission	22269 (29-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	M/s Jiangxi Synergy Pharmaceutical Co., LTD. This was Previously named as M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd. (As per API manufacture's Web information). **Certificate number** : JX20150013 **Validity: 05-03-2020**
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 17-07-2018 specifying import of lesinurad 3Kg (Batch No. 20180601BF) and 1 Kg (Batch No. 20180602BF) attested by AD DRAP, Karachi.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Arcox Tablet 90mg and 120mg on 17th September, 2018. The said inspection report was discussed in 286th meeting of Registration Board held on 14-16th November 2018 and the case was approved. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 17-07-2018 specifying import of lesinurad 3Kg (Batch No. 20180601BF) and 1 Kg (Batch No. 20180602BF) attested by AD DRAP, Karachi.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted an undertaking specifying that we have procured reference standard and impurity standards for testing / analysis purpose of Lesinurad from M/s Jiangxi Synergy Pharmaceutical Co Ltd. China in September 2018 through DHL courier. The DHL airway bill number for the said shipment is 1833140035.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	M/s Jiangxi Synergy Pharmaceutical Co., LTD. This was Previously named as M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd. (As per API manufacture's Web information). **Certificate number** : JX20150013 **Validity: 05-03-2020**
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist filled and signed by technical persons of the firm in March 2018, before the import of API.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted analytical report and copy of COA of API and reference and impurity standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for stability study of primary batches of Lesinurad tablets.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: 422DS01: 270 Tablet 422DS02: 270 Tablet 422DS03: 270 Tablet
QA / QC DATA		

12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing
	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
13.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
14.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches conducted as per the conditions of zone IV-A. The real time stability study data till 9 months is submitted by the firm. The stability initiation date of all batches is 15-07-2018.
15.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
16.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator "Zurampic" Tablets. The only difference is in film coating material. Therefore drug-excipient compatibility studies are not required.
17.	Record of comparative dissolution data.	Firm has only submitted comparative dissolution at 4.5 pH acetate buffer.
18.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator[3]:

Shortcomings communicated	Response by the firm
Justify how the comparative dissolution profile testing only at 4.5pH acetate buffer can demonstrate in vitro similarity against the innovator product, since the Appendix 1: Recommendations for conducting and assessing comparative dissolution profiles, of WHO guidelines Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability recommends that "*Studies should be performed in at least three media covering the physiological range, including pH 1.2 hydrochloric acid, pH 4.5 buffer and pH 6.8 buffer"*	Lesinurad is BCS Class II weak acid drug substance having solubility which increase with increase in pH. Considering the low solubility at low pH, FDA recommended dissolution medium was referred for CDP as it can discriminate the dissolution release.
Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting, since the USFDA approved innovator product "Zurampic" is discontinued.	Firm has submitted evidence of approval of Zurampic 200mg film coated tablet of Astrazaneca Pty Ltd which is approved by TGA Austalia and its status is "active"
GMP certificate of the API manufacturer, since the submitted certificate is issued by Jiangxi Fengxin Market and Quality Supervision Administration, which is not a relevant regulatory authority.	Firm has submitted that Chinese agency reforms, drug supervision and management were incorporated into the market supervision administration. Market supervision administration adopts hierarchical management. Drug supervision agencies are set up only at provincial / city level. The production, operations, and sale shall be undertaken by the city and county market

	supervision administration. Based on these it is clear that after Chinese agency reforms the relevant city / county market supervision administration will issue GMP certificate. The copy of Drug Manufacturing License (GAN 20160125) of M/s Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China. The certificate is valid till 15-02-2021.

Decision: Registration Board decided to approve registration of Lesiget Tablets 200mg with Innovator's specifications by M/s Getz Pharma (Pvt) Ltd. 29-30/27, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
2572	M/s Atco Laboratories Limited B-18, S.I.T.E., Karachi.	Ertumet Tablet 2.5mg/500mg Each film coated tablet contains: Ertugliflozin (as L-pyroglutamic acid) …….. 2.5 mg Metformin hydrochloride……..500 mg (Antidiabetic)	Form 5-D Diary No. 40970 06-12-2018 PKR.50,000/- 06-12-2018	Approved by USFDA Last inspection dated 28-02-2018 Panel recommends renewal of DML.
2573	M/s Atco Laboratories Limited B-18, S.I.T.E., Karachi.	Ertumet Tablet 2.5mg/1000mg Each film coated tablet contains: Ertugliflozin (as L-pyroglutamic acid) …….. 2.5 mg Metformin hydrochloride ……. 1000 mg (Antidiabetic)	Form 5-D Diary No. 40971 06-12-2018 PKR.50,000/- 06-12-2018	
2574	M/s Atco Laboratories Limited B-18, S.I.T.E., Karachi.	Ertumet Tablet 7.5mg/500mg Each film coated tablet contains: Ertugliflozin (as L-pyroglutamic acid) …….. 7.5 mg Metformin hydrochloride ……. 500 mg (Antidiabetic)	Form 5-D Diary No. 39911 04-12-2018 PKR.50,000/- 03-12-2018	
2575	M/s Atco Laboratories Limited B-18, S.I.T.E., Karachi.	Ertumet Tablet 7.5mg/1000mg Each film coated tablet contains: Ertugliflozin (as L-pyroglutamic acid) …….. 7.5 mg Metformin hydrochloride ……. 1000 mg (Antidiabetic)	Form 5-D Diary No. 39912 04-12-2018 PKR.50,000/- 03-12-2018	
	Remarks of Evaluator: • The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under: **(Dy.# 29427 dated 06-01-2020)**			

STABILITY STUDY DATA

Manufacturer of API	**Ertugliflozin:** Zhejiang Hongyuan Pharmaceutical Co. Ltd. Industrial zone Linhai Zhejiang Province

	Metformin hydrochloride: Ipca Laboratories Limited, H-4, MIDC, Waluj Aurangabad 431136 Mahrashtra India		
API Lot No.	**Ertugliflozin:** ET20180523		
	Metformin: 1807-00634		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1, 2, 3, 4 & 6 (months)		
ERTUMET TABLET 2.5MG/500MG			
Batch No.	271J18	272J18	273J18
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	02-11-2018	02-11-2018	02-11-2018
Date of Initiation	12-01-2019	12-01-2019	12-01-2019
ERTUMET TABLET 2.5MG/1000MG			
Batch No.	274J18	275J18	276J18
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	15-11-2018	15-11-2018	16-11-2018
Date of Initiation	12-01-2019	12-01-2019	12-01-2019
ERTUMET TABLET 7.5MG/500MG			
Batch No.	277J18	278J18	279J18
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	07-11-2018	07-11-2018	07-11-2018
Date of Initiation	12-01-2019	12-01-2019	12-01-2019
ERTUMET TABLET 7.5MG/1000MG			
Batch No.	280J18	281J18	282J18
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	21-11-2018	21-11-2018	21-11-2018
Date of Initiation	12-01-2019	12-01-2019	12-01-2019
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Documents To Be Provided		**Status**	
COA of API		Yes	
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.		**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20180032) issued by CFDA China. The certificate is valid till 14-03-2023.	
		Metformin: Firm has submitted copy of GMP certificate (No. 201703180) issued by office of the controller food and drugs administration Madhya Pradesh. The certificate is valid till 31-12-2021.	
Protocols followed for conduction of stability study		Yes	

and details of tests.		
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.		Yes
Documents confirming import of API etc.		**Ertugliflozin:** Firm has submitted copy of commercial invoice dated 28-05-2018 specifying import of 1 Kg Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 13-6-2018.
		Metformin: Firm has submitted copy of commercial invoice dated 27-06-2018 specifying import of 8000kg metformin HCl. The invoice is signed by AD (I&E) DRAP Karachi.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.		Yes
Commitment to continue real time stability study till assigned shelf life of the product.		Yes
Commitment to follow Drug Specification Rules, 1978.		Yes
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Rofl 500mcg tablet (Roflumilast)", which was conducted on 10th October, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "Roflumilast 500mcg Tablet (ROFL 500mcg TABLET)" by ATCO Laboratories Limited Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Audit trail reports on the testing were verifiable. iii. Adequate monitoring and control are available for stability chambers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin:** Firm has submitted copy of commercial invoice dated 28-05-2018 specifying import of 1 Kg Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 13-6-2018.
		Metformin: Firm has submitted copy of commercial invoice dated 27-06-2018 specifying import of 8000kg metformin HCl. The invoice is signed by AD (I&E) DRAP Karachi.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard and impurity.

4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20180032) issued by CFDA China. The certificate is valid till 14-03-2023.
		Metformin: Firm has submitted copy of GMP certificate (No. 201703180) issued by office of the controller food and drugs administration Madhya Pradesh. The certificate is valid till 31-12-2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor's audit form and SOPs for selection of vendor.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, and reference standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized general protocols/SOPs for the development & testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: **ERTUMET TABLET 2.5MG/500MG** 271J18: 375 Tablets 272J18: 375 Tablets 273J18: 375 Tablets **ERTUMET TABLET 2.5MG/1000MG** 274J18: 375 Tablets 275J18: 375 Tablets 276J18: 375 Tablets **ERTUMET TABLET 7.5MG/500MG** 277J18: 375 Tablets 278J18: 375 Tablets 279J18: 375 Tablets **ERTUMET TABLET 7.5MG/1000MG** 280J18: 375 Tablets 281J18: 375 Tablets 282J18: 375 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	**Ertugliflozin:** The submitted stability data as per zone IV-A conditions. The real time stability data is till 24 months. **Metformin:** Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies &

		long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted drug excipient compatability studies through binary mixtures study for all applied strengths.
18.	Record of comparative dissolution data.	• Firm has submitted that we have performed CDP for 2.5/1000mg and 7.5/500mg strength because the innovator pack of only these two strengths was available. • Firm has submitted data of comparative dissolution profile at pH 1.2 buffer, 4.5 buffer, 6.8.phosphate buffer and calculated difference of % release with innovator product for only 2 strengths.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC[3]:

Shortcomings communicated	Response by the firm
Justification why the dissolution test is not included in the finished product specification, further justify why the dissolution test is not performed during the stability studies.	Firm has not submitted any clarification however firm has submitted results of dissolution of all batches at 16 month time point during real time studies. Firm has also submitted revised finished product specifications containing dissolution test.

Decision: Deferred for scientific justification for not perfoming dissolution studies since innovator has performed dissolution test with limits of NLT Q in 15min

Case no. 06 Miscellaneous Cases

2576. Withdrawal of Registration applications of applied generic drug products of Abbott Laboratories (Pakistan) Ltd.

M/s Abbott Laboratories (Pakistan) Ltd have applied for registration of following products on Form 5F (CTD).

Sr. No	Applied Product	Generic Name	Date of Submission
1	PreAbb 25mg Capsule	Pregabalin	Form-5F Dy. No 5098 dated 03-05-2019 Rs.20,000/- Dated 03-05-2019
2	PreAbb 50mg Capsule	Pregabalin	Form-5F Dy. No 5099 dated 03-05-2019 Rs.20,000/- Dated 03-05-2019
3	PreAbb 75mg Capsule	Pregabalin	Form-5F Dy. No 33454 dated 09-10-2018 Rs.100,000/- Dated 09-10-2018
4	PreAbb 150mg Capsule	Pregabalin	Form-5F Dy. No 33455 dated 09-10-2018 Rs.100,000/- Dated 09-10-2018
5	PreAbb 300mg Capsule	Pregabalin	Form-5F Dy. No 5100 dated 03-05-2019 Rs.20,000/- Dated 03-05-2019
6	Abistat 120mg Capsule	Orlistat	Form-5F Dy. No 5096 dated 03-05-2019 Rs.20,000/- Dated 03-05-2019

The applications were evaluated and letter of shortcoming were issued.
Now the firm vide their letter dated 17-06-2020 has requested to withdraw these registration applications due to availability of better molecules.
The request of the firm is submitted before the Board.

Decision: Registration Board acceded to the firm's request to withdraw above registration applications and rejected / disposed off above 6 applications.

Case No.1. Request of M/s Amarant Pharmaceuticals, Karachi for correction in pack size/ volume of Amta-Rose Injection.

Registration Board in its 290th meeting approved the following product M/s Amarant Pharmaceutical (Pvt) Ltd., 158-D Tore, Gadap Road, Super Highway Karachi with contract manufacturing from M/s Caraway Pharmaceutical, Islamabad:

Contract Giver / Applicant	Contract Acceptor / Manufacturer
M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158, D. Tore, Gadap Road, Super Highway, Karachi.	M/s Caraway Pharmaceuticals Plot No. 12, street # N-3, National Industrial Zone, Rawat, Islamabad.

Amta-Rose Injection

1. Name of drug(s)
Amta-Rose Injection (Iron Sucrose)

2. Composition
Each ampoule (1ml) contains: Iron Sucrose Complex eq. to Elemental Iron…100mg

3. Dosage Form
Injection

4. Form, Fee, DY Date
Form 5
1024 dated 02-05-2013
Rs 150,000/-

5. Decision of Registration Board in 246th meeting
Deferred for rectification of following observation in the dossier:

i. Reference will be sent to B & A Division for verification of challan.
ii. Confirmation of installation and operational qualifications for TOC analyzer and liquid particle counter by the area FID.
iii. Initially on Form 5, firm mentioned quantity of active as 420 mg/ ampoule, in reply firm mentioned it as 1873 mg/ ampoule. Clarification is required. No clarification is provided in second reply.
iv. Letter of approval of injection section is required. Not provided in second reply. Inspection report dated 24-09-12 mentions Ampoule and Vial sections.

Submission by the Firm:

6. The original dossier of the firm has been traced with original fee deposit slip.
ii. Evidence of Approval status in Reference regulatory authorities
iii. Firm has submitted Approval of Liquid Ampoule (Injectable) manufacturing facility from Licensing Division
iv. Correct labelling information for treatment of Vit-D3 deficiency.

The original dossier has been traced out with original fee challans. Moreover, the firm has submitted following documents in support:

7. Justification of point raised in point No. 5
8. Undertaking of installation of TOC and liquid practical counter.
9. Section approval dated 15.04.2015.

Decision 271st Meeting of Registration Board:

Registration Board deferred the request of M/s Amarant Pharmaceuticals Karachi for submission of latest GMP report of M/s Amarant Pharmaceuticals, Karachi (contract giver / applicant) and M/s Caraway Pharmaceuticals, Rawat, Islamabad (contract acceptor / manufacturer).

Later on, the firm submitted the inspection reports in favor of M/s Amarant Pharmaceuticals, Karachi conducted on 26-February-2019 and M/s Caraway Pharmaceuticals, Rawat, Islamabad conducted on 24-July-2018, respectively.

Decision of M-290:

Registration Board approved registration of above mentioned products of M/s Amarant Pharmaceuticals, Karachi on contract manufacturing basis by M/s Caraway Pharmaceuticals, Rawat, Islamabad.

The case was re-considered in 295th meeting of Registration Board (held on 8th-11th June, 2020) wherein the Board was informed that registration letter could not be issued as demanded pack size was not mentioned in minutes of 290th meeting. Furthermore, as per minutes the firm had applied: **"Each ampoule (1ml) contains: Iron Sucrose Complex eq. to Elemental Iron…100mg"**

However, the standard formulation approved by reference regulatory authority states:

"**Each 5ml ampoule contains: Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron 100mg"**

Original Dossier/ Form-5 could not be retrieved. However, the firm had submitted revised label claim along-with fee of **Rs.5000/-** (DS#1908821 dated 27-12-2019) as per following details:

"Each 5ml ampoule contains:
Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron 100mg"

The firm had also informed that their demanded pack size and MRP is **"As Per SRO"**

Decision of M-295: Registration Board deferred for submission of remaining fee Rs.15000/-

The firm has now submitted remaining fee of Rs.15000 (DS#1952631) for change in label claim (Dy.No.19506 dated 10-08-2020).

Decision: **Registration Board approved the request of M/s Amarant Pharmaceuticals (Pvt.) Ltd., Karachi for correction in pack size/ volume along-with composition/ label claim of Amta-Rose Injection in line with the reference/ standard product approved by Reference Regulatory Authorities. Detail is given as under:**

"Each 5ml ampoule contains:
Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron….100mg"
Demanded Pack Size and MRP: "As Per SRO"

Case No.2. Request of M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan for correction in Packaging Material/ Container Closure System of Atracurium Besylate Injections

Registration Board in its 290th meeting approved the following products of M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan Contract Manufactured By: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore
Brand Name +Dosage Form + Strength	Atracurium Besylate 25mg/2.5ml Injection
Composition	Each 2.5ml vial contains: Atracurium Besylate…….25mg
Diary No. Date of R& I & fee	Dy. No 17946 Dated 15-05-2018, Rs. 50,000/- 15-05-2018
Pharmacological Group	muscle relaxant
Type of Form	Form 5
Finished product Specifications	USP Specification
Pack size & Demanded Price	5'sx2.5ml
Approval status of product in Reference Regulatory Authorities	Atracurium 10mg/ml Solution for Injection or Infusion (UK)
Me-too status	Efacurim 25mg /2.5ml I.V Injection of M/s Pharmedic
GMP status	Last GMP inspection dated 5th & 27th December conclusion by Panel "The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection"
Remarks of the Evaluator	
Decision: Approved	

Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan Contract Manufactured By: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore
Brand Name +Dosage Form + Strength	Atracurium Besylate 50mg/5ml Injection
Composition	Each 5ml vial contains: Atracurium Besylate…….50mg
Diary No. Date of R& I & fee	Dy. No 17947 Dated 15-05-2018, Rs. 50,000/- 15-05-2018
Pharmacological Group	muscle relaxant
Type of Form	Form 5
Finished product Specifications	USP Specification
Pack size & Demanded Price	5'sx5ml
Approval status of product in Reference Regulatory Authorities	Atracurium 10mg/ml Solution for Injection or Infusion (UK)
Me-too status	Arium Injection 50Mg of M/s Cirin
GMP status	Last GMP inspection dated 5th & 27th December conclusion by Panel "The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection"
Remarks of the Evaluator	
Decision: Approved	

The case was re-considered in 295th meeting of Registration Board (held on 8th-11th June, 2020) wherein the Board was informed that registration letter had been issued. However, the firm later on informed that their applied packaging material was "**Ampoule**" instead of "**Vial**". Original Dossier/ Form-5 couldn't be retrieved, however, the firm had submitted copy of form-5 wherein "Ampoule" is mentioned on 1st page and against S.No. 4 (strength of active ingredient per unit). Furthermore, the firm had also submitted a copy of approval for addition section issued to M/s NovaMed Pharmaceuticals (Pvt.) Ltd., Lahore (Contract Manufacturer) vide letter No.F.6-1/2013-Lic (M-232) dated 29-08-2013 stating following sections:

1. General Liquid Injection (Ampoule)
2. General Liquid Injection Vial (SVP)

Decision of M-295: Registration Board deferred the case for verification of applied packaging material/container closure system from original dossier submitted by the firm at the time of initial application.

Despite of repeated attempts, original dossier/ Form-5 couldn't be retrieved. However, the firm has now submitted snap shots of registered brands in Pakistan and PIL of following products as evidence for availability of applied product in "**ampoule**" packaging material:

Local Availability				
S.No.	**Brand Name**	**Strength**	**Reg.No.**	**Reg. Holder**
1.	Tracurium	2.5ml 5ml	009570 009571	GSK
2.	Atrelex	2.5ml 5ml	018010 011031	Abbott
3.	Acuron	3ml 5ml	022818	Brookes
International/RRA Availability				
S.No.	**Brand Name**	**Strength**	**License Holder**	**Approved in Country**
1.	Tracrium	2.5ml 5ml	GlaxoSmithKline	Australia/New Zealand
2.	Atracurium Besylate	2.5ml 5ml	Hospira UK Limited	UK

Decision: **Keeping in view the availability/ approval status of generic products and reference/ standard products (approved by Reference Regulatory Authorities) in both "Vial" and "Ampoule" container closures, Registration Board acceded to the request of M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan for correction in Packaging Material/ Container Closure System of Atracurium Besylate Injections from "Vial" to "Ampoule".**

Case No.3. Request of M/s Barret Hodgson, Karachi for correction in Demanded MRP of Opsilk Lubricant Eye Drops

Registration Board in its 275th meeting approved Opsilk Lubricant Eye Drops of M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.
Brand Name +Dosage Form + Strength	Opsilk Lubricant eye drops
Composition	Each ml contains: Polyethylene Glycol 400 …… 4 mg Propylene Glycol …….. 3 mg
Diary No. Date of R& I & fee	Dy. No.46; 06-07-2015; Rs.20,000/- (06-07-2015)
Pharmacological Group	Ocular lubricant
Type of Form	Form-5
Finished product Specification	Manufacturer specifications
Pack size & Demanded Price	**10ml; Rs.33.35/- 15ml; Rs.19.55/-** **30 ml; Rs. 575/-**
Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
Me-too status	Systane Lubricant Eye Drops M/s Ali Gohar & Company (Pvt) Ltd., Karachi (Reg.# 044834)
GMP status	Last inspection report dated 8-8-2017 confirms satisfactory compliance to GMP
Remarks of the Evaluator.	
Decision: Approved with innovator's specification.	

The case was re-considered in 295th meeting of Registration Board (held on 8th-11th June, 2020) wherein the Board was informed that price had not been fixed for demanded pack sizes. Furthermore, MRP demanded for 10ml pack appeared to be less than that approved for 5ml pack vide 12th DPC. Accordingly, as per practice in vogue, the case was referred to C&P Division for Price confirmation/fixation.

However, the firm had informed that there were discrepancies in demanded prices mentioned in M-275 (held on 25th - 27th Oct, 2019) and their applied demanded prices as per following details. Furthermore, the firm had also stated that they intimated timely via letter dated 2-04-2018. In this regard, the firm had also submitted copy of form-5 along-with undertaking because the original dossier couldn't be retrieved.

S/N	Pack Size	Actual Demanded Price On Form-5 at the Time of Registration Application	Demanded Price Erroneously Mentioned in Minutes of 275th Meeting
I	**II**	**III**	**IV**
1.	10ml	Rs.210/-	Rs.33.35/-
2.	15 ml	Rs.300/-	Rs.19.55/-
3.	30ml	Rs.575/-	Rs.575/-

Decision of M-295: Registration Board deferred the case for verification of demanded MRP from original dossier submitted by the firm at the time of initial application.

Original dossier has now been received from PEC (Dy. No.46; 06-07-2015) from where the above mentioned claim of the firm regarding demanded pack sizes & demanded prices (column II & III of above table) has been verified.

Decision: **Registration Board acceded to the request of M/s Barret Hodgson Pakistan, Karachi for correction in demanded MRP of Opsilk Lubricant Eye Drops as per details mentioned vide column II and III of above table.**

Case No.4. Change in Registration Status of Etipro 20mg Capsules From M/s The Searle Company, Limited, Karachi to M/s ICI Pakistan Limited (Formerly Cirin Pharmaceuticals (Pvt.) Ltd.), Hattar

Registration Board in its 295th meeting (held on 8th-11th June, 2020) considered the request of M/s ICI Pakistan Limited (Formerly Cirin Pharmaceuticals (Pvt.) Ltd.), 32/2A Phase 3, Industria Estate, Hattar (DML # 000363) for change in registration status of "**Etipro 20mg (Omeprazole) Capsules**" from M/s The Searle Company Limited, Karachi to their name as per following details:

I	II	III	IV	V
Reg. No.	**Brand name and Composition as per Initial Registration Letter**	**Brand Name & Revised Composition applied by M/s ICI**	**Remarks of RRR section Regarding Renewal Status**	**Dy. No. & Date of Submission**
019147	**Etipro SR 20mg Capsule** Each capsule contains:- Omeprazole ……..20mg as SR Microgranules **(Toll manufacture for ICI Pak Limited, Karachi)** **Source of Pellets:** M/s Precise Chemipharm a Pvt Ltd, India.	**Etipro 20mg Capsule** Each capsule contains:- Omeprazole Enteric Coated Pellets eq. to Omeprazole……..20mg (USP Specifications) **Source of Pellets:** M/s Precise Chemipharm a Pvt Ltd, Gut No. 215/1 & 215/2, Khatwad Phata, At Psot Talegaon, Taluka Dindori, Nashik 422202 Maharashtra State, India **India.**	As per computer record of RRR section, renewal application is received on 06-04-2016 and initial date of registration is 10-04-1996. Firm has submitted additional fee in case of imported pellets on 27-02-2018. Case has to be placed before the Reg. Board for regularization and final status will be communicated afterwards	Initial application submitted by M/s Cirin Pharmaceuticals, Hattar; Dy. No.113; 26-01-2018 **with Fee of** Rs. 100000/- (Challan No. 0713297). After change in title, fresh application has been received from M/s ICI Pakistan Limited; Dy. No.606; 03-06-2020 **with Fee of** Rs. 100000/- (Challan No. 1959577).

The firm has now submitted following documents:

i. Capsule (General) Section approval of M/s Cirin, Hattar verified from Licensing Division's letter for renewal of DML (dated 02nd March, 2016).
ii. Copy of last GMP inspection report of M/s Cirin Pharmaceuticals (Pvt.) Ltd.), 32/2A Phase 3, Industria Estate, Hattar dated 07th May, 2018 indicating "Good" level.
iii. NOC from M/s The Searle Company Limited, Karachi dated 01-06-2020.
iv. DML of M/s Cirin, Hattar dated 18-09-2015.
v. Copy of approval for change in title and management of M/s Cirin, Hattar issued by Licensing Division dated 18-02-2020.

vi. Copy of GMP certificate of M/s Chemipharma, India valid upto 27-02-2022. However, the firm had previously submitted legalized GMP Certificate valid upto 22-01-2019 along-with Accelerated & Real Time statbility studies.

Decision of M-295: Registration Board deliberated the case in correlation with succeeding Case and directed the firm to submit clarification/justification for their instant request as they already hold registration of same molecule in same dosage form & strength i.e., Acizol (Omeprazole) Caps 20mg (Reg. No. 017715).

M/s ICI Pakistan Limited, Hattar has now submitted following clarification on the above matter:

"ICI Pakistan is marketing Etipro 20mg Caps, currently registered in the name of The Searle Company Limited (Searle) since its registration in 1996. It is ICI's famous brand in Pakistan therefore we want to shift its registration in the name of ICI Pakistan at the earliest. Initially Cirin Pharmaceuticals (Pvt) Limited (Cirin, a wholly owned subsidiary of ICI Pakistan Limited) had applied for transfer of registration from Searle to Cirin by paying fee of Rs. 100,000/- but the application could not be processed because Acizole 20mg caps having same molecule was registered in the name of Cirin.

Recently title of Cirin has been changed to ICI Pakistan limited and we have obtained fresh NOC from Searle in the name of ICI Pakistan Limited and request to process our pending application by paying an additional fee of Rs. 100,000/- following DRAP requirement.

Further, we have submitted all the documents required for withdrawal of Acizol 20mg Caps (Reg. No. 017715) registration.

We request the Registration Board for de-registration of Acizol 20mg and at the same time approve our subject application for change of registration status of Etipro 20mg Caps from Searle to ICI Pakistan limited, 32-2A, Phase III, Industrial Estate, Hattar (DML No: 000363)."

Decision: Registration Board decided as follows:

i. **Cancellation of registration of Etipro SR 20mg Capsule (R#019147) from the name of M/s The Searle Company Limited, F-319, S.I.T.E, Karachi.**
ii. **Approved registration of Etipro 20mg Capsule in the name of M/s. ICI Pakistan Limited, 32/2A, Phase III, Industrial Estate, Hattar, Haripur. In line with the reference/ standard product approved by Reference Regulatory Authorities, label claim shall be standardized as mentioned vide column III of above table. Furthermore, the firm shall submit valid and legalized GMP of M/s Precise Chemipharm, India before issuance of Registration letter.**
iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.5. Request for Withdrawal of Registration of Acizol (Omeprazole) Caps 20mg (Reg. No. 017715)

Registration Board in its 295th meeting (held on 8th-11th June, 2020) considered the request of M/s ICI Pakistan Limited. 32/2 A, Industrial Estate Hattar (Formerly known as Cirin Pharmaceuticals (Pvt.) Limited - DML No. 000363) to withdraw an existing registration of Acizol 20mg (registered in the name of M/s Cirin, Hattar) & to expedite their application for change in registration status of Etipro Caps 20mg (R# 019147) from M/s the Searle Company Limited, Karachi to M/s ICI Pakistan Limited, Hattar.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	017715	Acizol Capsule 20mg Each Capsule contains: Omeprazole…..20mg	To expedite their application for change in registration status of Etipro Caps 20mg (R# 019147) from M/s the	1. Alpazol of M/s Medicaids Pakistan (Pvt) Ltd. 2. Amazole of M/s Medera	Reg. Letter date: 18-07-1995 Last Renewal date:

			Searle Company Limited, Karachi to M/s ICI Pakistan Limited, Hattar.	Pharmaceuticals (Pvt). 3. Anmol of M/s Roryan Pharmaceutical Industries.	10-07-2015

The firm has now submitted following documents:

- Copy of registration letters and Last renewal.
- List of alternatives brands available in Pakistan
- An Undertaking that:
    i. No case is pending at any forum/ court of law regarding above mentioned products.
    ii. Provided information/ documents are true/ correct.

Decision of M-295: Registration Board deferred the case to be considered after submission of clarification/ justification in preceding Case.

Submitted for consideration of Registration Board in the light of clarification submitted by M/s ICI Pakistan Limited, Hattar in preceding case.

Decision: **Registration Board acceded to the request of M/s. ICI Pakistan Limited (Formerly: Cirin Pharmaceuticals (Pvt.) Limited), 32/2A, Phase III, Industrial Estate, Hattar, Haripur for withdrawal/ de-registration of Acizol Capsule 20mg (Reg. No. 017715) as the same molecule i.e., "Omeprazole" under the brand name of "Etipro 20mg Capsule" has been approved for registration in their name after being cancelled from M/s The Searle Company Limited, Karachi.**

Case No.6. **Request of M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi for Revision of Formulation of Eskazole Tablets 400mg**

Registration Board in its 288th meeting approved Eskazole Tablets 400mg of M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi
Brand Name +Dosage Form + Strength	Eskazole Tablets 400mg
Composition	Each film coated tablet contains: Albendazole …400mg
Diary No. Date of R& I & fee	Dy.No 5185 dated 13-02-2018 Rs. 20,000/- 12-02-2018
Pharmacological Group	ANTHELMINTICS
Type of Form	Form 5
Finished product Specifications	USP
Pack size & Demanded Price	2's, 7's, 14's, 20's, 28's, 30's & 60's RS: 200/2's, 700/7's, 1000/10's,1400/14's 2000/20's, 2800/28's, 3000/30's & 6000/60's
Approval status of product in Reference Regulatory Authorities	Eskazole 400mg tablet by GSK Austrailia
Me-too status (with strength and dosage form)	Wormgo Tablets of M/s Mediceena Pharma
GMP status	Last GMP inspection was conducted on 21-07-2017 and report concludes that firm was considered to be operating at good level of compliance
Remarks of the Evaluator[4]	
Decision: Approved.	

However, while processing for issuance of registration letter it was observed that the standard formulation approved by TGA (Eskazole 400mg tablet by GSK Australia; quoted as reference product in M-

288) is a chewable tablet. Therefore, clarification was sought from the firm/ dossier regarding applied formulation/ RRA approval status. In response, the firm has now submitted fresh fee for Rs. 20,000/- along with requisite documents for revision of formulation to "**chewable tablet**" (Dy. No. 2263 dated 21-02-2020).

Decision: **Registration Board acceded to the request of M/s Atco Laboratories Limited, B-18, S.I.T.E. Karachi for revision of formulation of Eskazole Tablets 400mg in line with reference/ standard product approved by Reference Regulatory Authorities. Detail is as under:**

"Each chewable tablet contains:
Albendazole……..…400mg"

Case No.7. Request of M/s Martin Dow Limited, Karachi for import of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has informed that they are going to shift their imported registered product "Rivotril Tablet 0.5mg (Reg.No. 001049)" and "Rivotril Tablet 2mg (Reg.No. 003626)" from bulk import to local manufacturing. In this regard, they are going to perform development & stability studies for the said product. Accordingly, the firm has requested for permission to import a controlled drug substance "**Clonazepam**" for developing their product. Details are as under:

S.No	Controlled Drug Substance	Quantity required for trial, development & stability batches	Source
1	Rivotril Tablet 0.5mg (Reg.No. 001049)	0.0265kg	Fabbrica Italiana Sintetici S.p.a, Italy
2	Rivotril Tablet 2mg (Reg.No. 003626)	0.076kg	
	Total	**0.1025kg**	
3	Clonazepam Working Standard	0.400 g	
4	Clonazepam Related Compound A	0.025g	
5	Clonazepam Related Compound B	0.025g	
6	Clonazepam Related Compound C	0.025g	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Clonazepam 0.5mg

S.NO.	Product	API	mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Clonazepam 0.5mg tablet**	Clonazepam	0.5	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Pilot batch 2**	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	16.50	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	26.50

				(10,000 tablets				

ii. Clonazepam 2mg

S.NO.	Product	API	mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Clonazepam 2mg tablet**	Clonazepam	2.00	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Pilot batch 2** (10,000 tablets	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	66.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	76.00

The firm has also submitted evidence for approval of requisite manufacturing facility in the form of letter issued by Licensing Division dated 12-06-2011 stating approval of additional sections including **"Tablet (Psychotropic) (Product already registered)".**

Decision: **Registration Board decided to recommend allocation of controlled drug substances i.e., Clonazepam along-with above mentioned Reference Standards for trial/stability batches of above mentioned products.**
The Board further advised the firm to maintain records of used substances and waste materials having above APIs and shall be destroyed after approval of Controlled Drug Division, DRAP.

Case No.8. Request of M/s Martin Dow Marker Limited, 7, Jail Road Quetta for import of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s Martin Dow Marker Limited, 7, Jail Road Quetta has requested for permission to import controlled drug substances for trial/development and stability Purposes. Details are given below:

i. <u>Diazepam</u>

S.No	Controlled Drug Substance	Quantity required for trial, development & stability batches	Source
1	Diazepam Injection 10mg/2ml	98.5 g	Fabbrica Italiana Sintetici S.p.a, Italy
2	**Total**	**100 g**	
3	Diazepam Working Standard	200mg	
4	Diazepam Related Compound A	100 mg	
5	Diazepam Related Compound B	100 mg	
6	Diazepam USP nordazepam RS	100 mg	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S.No.	Product	API	Mg/2mL	No. of Tab/batch	No. of batches	Quantity of API required			
1.	Diazepam Injection 10mg/2ml	Diazepam	10 mg	Batch size for trial batch (2500 ampoules) Actual Batch Size (2325 Ampoules) Filled Volume / Ampoule as per USP (2.15mL)	Trial + Stability	For Formulation Development	For QC analysis	Testing + Reference Samples	Total
						g	g	g	g
					Trial batches (3)	75g (3 Trial batches)	6	17.5	98.5

ii. <u>Midazolam</u>

S.No	Controlled Drug Substance	Quantity required for trial, development & stability batches	Source
1	Midazolam Injection 5mg/5ml	50g	Fabbrica Italiana Sintetici S.p.a, Italy
	Total	**50g**	
3	Midazolam CIV	600mg	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S.No.	Product	API	mg/5mL	No. of Ampoule/batch	No. of batches	Quantity of API required			
1.	Midazolam Injection 5mg/5ml	Midazolam	5 mg	Batch size for trial batch (1000 ampoules) Actual Batch Size (943 Ampoules) Filled Volume / Ampoule as per USP (5.30mL)	Trial + Stability	For Formulation Development	For QC analysis	Testing + Reference Samples	Total
						g	g	g	g
					Trial batches (3)	15 (3 Trial batches)	10	25	50

Decision: Registration Board deferred the case for confirmation of approval status of requisite manufacturing facility i.e., "Injection (Psychotropic)".

Case No.9. Request of M/s Sayyed Pharmaceutical Industries (Pvt) Ltd, Hattar for Import of Controlled Drug Substances for Trial/Development and Stability Purposes.

M/s Sayyed Pharmaceutical Industries (Pvt) Ltd.,67/2, Phase 3, Industrial Estate, Hattar has requested for permission to import controlled drug substances for trial/development and stability Purposes as required in Form-5F. Details are given below:

A. Lorazepam

S.No	Product Name	Quantity Required	Source
1	Lorazepam tablet 1 mg	43.00gm	**Centaur Pharmaceuticals Pvt. Ltd. API Division Plot Nos.75,76 & 76/1,Chikhloli MIDC Ambernath (West) District:Thane-421501 Maharashtra (India)**
2	Lorazepam tablet 2 mg	66.00gm	
	Total	**109.00gm**	
3	Lorazepam working standard	600mg	
4	Lorazepam Related compound A	30mg	
5	Lorazepam Related compound B	30mg	
6	Lorazepam Related compound C	30mg	
7	Lorazepam Related compound D	30mg	
8	Lorazepam Related compound E	30mg	

The breakup of quantities is as follows:

i. Lorazepam 1mg

S.No	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Lorazepam 1mg Tablet**	Lorazepam	**1.0**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	33.00	For chemical testing:5.0 Retention sample:5.00 Total:10.0	43.00

ii. Lorazepam 2mg

S.No	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Lorazepam 2mg Tablet**	Lorazepam	**2.00**	**Batch size for trial batch** (1,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g

				Batch size of Lab batch (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial batches (3) Stability batches (3)	66.00	--	66.00

B. <u>Phenobarbitone</u>

S.No	Product Name	Quantity Required	Source
1	Phenobarbitone tablet 1 mg	1000.0gm	**Nantong Jinghua Pharmaceutical Co., Ltd., ADD: No. 20,3 Haibin Road, Yanhai Economic Development Zone, Rudong. Nantong, Jiangsu, China, 226407**
	Total	**1000.0gm**	
2	Phenobarbitone working standard	600mg	

The breakup of quantities is as follows:

<u>S.No</u>	**Product**	**API**	**Mg/Tab**	**No of Tab/batch**	**No of batches**	**Quantity of API Required**		
1.	**Phenobarbitone tablet 1 mg**	Phenobarbitone	30	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2**	Trial + Stability	For formulation development	For QC testing and retention	Total
						<u>g</u>	<u>g</u>	<u>g</u>
					Trial batches (3) Stability batches (3)	990.00	For chemical testing:5.0 Retention sample:5.00 Total:10.0	1000.0

				(10,000 tablets)				

The firm has also submitted evidence for approval of requisite manufacturing facility in the form of letter issued by Licensing Division dated 09-04-2020 stating approval of additional section i.e., **"Tablet (Psychotropic)"**

Decision: **Registration Board decided to recommend allocation of controlled drug substances i.e., i) Lorazepam ii) Phenobarbitone along-with above mentioned Reference Standards for trial/stability batches of abovementioned products.**
The Board further advised the firm to maintain records of used substances and waste materials having above APIs and shall be destroyed after approval of Controlled Drug Division, DRAP.

Case No.10. Request of M/s Roryan Pharmaceutical Industries (Pvt) Ltd, Peshawar for Import of Controlled Drug Substances for Trial/Development and Stability Purposes.

M/s Roryan Pharmaceutical Industries (Pvt) Ltd, Peshawar has requested for permission to import controlled drug substances for trial/development and stability Purposes as required in Form-5F. Details are given below:

S.No	Product Name	Quantity Required	Source
1	Zolpidem Tartrate tablet 10 mg	340.00gm	**AArthi Drugs Ltd., E-22 MIDC, Tarapur, Tal-Palghar, Dist- Thane 401506 Maharashtra State, India**
	Total	**340.00gm**	
2	Zolpidem Tartrate working standard	200mg	
3	Zolpidem Related compound A	15mg	

The breakup of quantities is as follows:

No	**Product**	**API**	**Mg/Tab**	**No of Tab/batch**	**No of batches**	**Quantity of API Required**		
1.	**Zolpidem Tartrate tablet 10 mg**	Zolpidem Tartrate	**10mg**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	330.00	For chemical testing:5.0 Retention sample:5.00 Total:10.0	340.00

The firm has also submitted evidence for approval of requisite manufacturing facility in the form of letter issued by Licensing Division dated 26-01-2011 stating approval of additional section i.e., **"Tablet (Psychotropic)"**

Decision: **Registration Board decided to recommend allocation of controlled drug substances i.e., Zolpidem along-with above mentioned Reference Standards for trial/stability batches of Zolpidem Tartrate tablet 10 mg.**
The Board further advised the firm to maintain records of used substances and waste materials having above APIs and shall be destroyed after approval of Controlled Drug Division, DRAP.

Case No.11. Request of M/s Sami Pharmaceutical (Pvt) Ltd, Karachi for Import of Controlled Drug Substances for Trial/Development and Stability Purposes.

M/s Sami Pharmaceutical (Pvt) Ltd, Off. Hub River Road, S.I.T.E Karachi has requested for permission to import controlled drug substances for trial/development and stability Purposes. Details are given below:

OXYCODONE HCl

S. No.	Product Name	Quantity Required (g)	Source
1.	Oxycodone 10mg/ml Injection	135	**M/s. Francopia** 20 Avenue Raymond Aron, 92165 Antony Cedex **France**
2.	Oxycodone 40mg + Naloxone 20mg Prolonged Release Tablets	400	
3.	Oxycodone 20mg + Naloxone 10mg Prolonged Release Tablets	200	
4.	Oxycodone 10mg + Naloxone 5mg Prolonged Release Tablets	100	
5.	Oxycodone 20mg Capsules	200	
6.	Oxycodone 10mg Capsules	100	
7.	Oxycodone 5mg Capsules	50	
8.	For QC Testing	15	
9.	**Total**	**1200g**	
10.	Oxycodone HCl Reference Standard	70mg	European Directorate for the quality of Medicines & HealthCare (EDQM) EDQM- Council of Europe, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France.
11.	Oxycodon Impurity	50mg	

1) OXYCODONE 10mg/ml Injection

S. No.	Product	API	Mg/ Ampoule	No. of Amp/batch	No. of Batches	Quantity of API Required		
01.	Oxycodone 10mg/ml Injection	Oxycodone	10	**Batch Size for Trial Batch** (3375 Ampoules) **Batch Size for Lab Scale Batch 01** (3375 Ampoules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g

				Batch Size for Lab Scale Batch 02 (3375 Ampoules) **Batch Size for Lab Scale Batch 03** (3375 Ampoules)	**Trial batch (1)** **Stability Batches (3)**	**135**	For Chemical Testing: **5.00** Retention Sample+ Working Standard+ Validation : **10.00** **Total: 15.00**	**150**

2) <u>OXYCODONE 40mg + NALOXONE 20mg Prolonged release Tablets</u>

S. No.	**Product**	**API**	**Mg/ Tab.**	**No. of Tablets/batch**	**No. of Batches**	**Quantity of API Required**		
01.	OXYCODONE 40mg + NALOXONE 20mg Prolonged release Tablets	Oxycodone	40	**Batch Size for Trial Batch** (2500 Tablets) **Batch Size for Lab Scale Batch 01** (2500 Tablets) **Batch Size for Lab Scale Batch 02** (2500 Tablets) **Batch Size for Lab Scale Batch 03** (2500 Tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**400**	**--**	**400**

3) <u>OXYCODONE 20mg + NALOXONE 10mg Prolonged release Tablets</u>

S. No.	**Product**	**API**	**Mg /Tab.**	**No. of Tablets/batch**	**No. of Batches**	**Quantity of API Required**		
01.	OXYCODONE 20mg + NALOXONE 10mg Prolonged release Tablets	Oxycodone	20	**Batch Size for Trial Batch** (2500 Tablets) **Batch Size for Lab Scale Batch 01** (2500 Tablets) **Batch Size for Lab Scale Batch 02** (2500 Tablets) **Batch Size for Lab Scale Batch 03** (2500 Tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**200**	**--**	**200**

4) <u>OXYCODONE 10mg + NALOXONE 5mg Prolonged release Tablets</u>

S. No.	Product	API	Mg /Tab.	No. of Tablets/batch	No. of Batches	Quantity of API Required		
01.	OXYCODONE 10mg + NALOXONE 5mg Prolonged release Tablets	Oxycodone	10	**Batch Size for Trial Batch** (2500 Tablets) **Batch Size for Lab Scale Batch 01** (2500 Tablets) **Batch Size for Lab Scale Batch 02** (2500 Tablets) **Batch Size for Lab Scale Batch 03** (2500 Tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**100**	**--**	**100**

5) <u>OXYCODONE 20mg Capsules</u>

S. No.	Product	API	Mg/ Cap.	No. of Capsules/batch	No. of Batches	Quantity of API Required		
01.	OXYCODONE 20mg Capsules	Oxycodone	20	**Batch Size for Trial Batch** (2500 Capsules) **Batch Size for Lab Scale Batch 01** (2500 Capsules) **Batch Size for Lab Scale Batch 02** (2500 Capsules) **Batch Size for Lab Scale Batch 03** (2500 Capsules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**200**	**--**	**200**

6) <u>OXYCODONE 10mg Capsules</u>

S. No.	Product	API	Mg/ Cap.	No. of Capsules/batch	No. of Batches	Quantity of API Required		
01.	OXYCODONE 10mg Capsules	Oxycodone	10	**Batch Size for Trial Batch** (2500 Capsules) **Batch Size for Lab Scale Batch 01** (2500 Capsules) **Batch Size for Lab Scale Batch 02** (2500 Capsules) **Batch Size for Lab Scale Batch 03** (2500 Capsules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**100**	**--**	**100**

7) <u>OXYCODONE 5mg Capsules</u>

S. No.	Product	API	Mg/ Cap.	No. of Capsules/batch	No. of Batches	Quantity of API Required		
01.	OXYCODONE 5mg Capsules	Oxycodone	5	**Batch Size for Trial Batch** (2500 Capsules) **Batch Size for Lab Scale Batch 01** (2500 Capsules) **Batch Size for Lab Scale Batch 02** (2500 Capsules) **Batch Size for Lab Scale Batch 03** (2500 Capsules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (1) Stability Batches (3)	**50**	**--**	**50**

The firm has also submitted evidence for approval of requisite manufacturing facility in the form of letter dated 22-06-2018, issued by Licensing Division for "Regularization of existing facility as per approved layout plan on the recommendations of the panel of experts" stating following sections:

- **Tablet (Psychotropic)**
- **Capsule (Psychotropic)**
- **Liquid Injectable-SVP (Psychotropic)**

Decision: **Registration Board decided to recommend allocation of controlled drug substances i.e., Oxycodone along-with above mentioned Reference Standard for trial/stability batches of above mentioned products.**
The Board further advised the firm to maintain records of used substances and waste materials having above APIs and shall be destroyed after approval of Controlled Drug Division, DRAP.

Case No.12. Request of M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd, Jamshoro Regarding Interim Extension for Utilization of Printed Packaging Material Bearing Old Registration Numbers and Pharmacopeia Specification.

M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd, Petaro Road, Jamshoro (DML #000010) was issued registration of 04 products (Panadol Tablet, Children's Panadol Liquid, Children's Panadol Drops & Panadol Extra Tablets) through contract manufacturing at M/s Pharmatec, Karachi (contract manufacturer remains same) after being cancelled from M/s GSK Pakistan Limited, F-268, Karachi. The firm, later on, requested for permission to resume manufacturing of all products, considered as essential medicine (containing paracetamol) till 31st July, 2020 with existing registration numbers to consume entire inventory with continuous and un-interrupted supply of products. In support of their request, the firm mentioned that they had been awarded new registration numbers, therefore, they require time to print new artwork with new registration numbers.

The firm was advised to submit requisite documents along-with relevant rules applicable to their request for utilization of printed packaging material bearing old registration numbers.

However, the firm has once again requested for interim extension till **31st October, 2020** for utilization of printed packaging material bearing old registration numbers and specifications. The firm has further

mentioned that current COVID-19 lockdown situation is further impacting timely delivery of these components as most of the material is coming from China.

Decision: **Registration Board deferred the case & directed the firm to provide rule position applicable to their request for utilization of printed packaging material bearing old registration numbers.**

Case No.13. Violation of Registration Board's Decision on Segregated Section for Psychotropic Products by M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi

Assistant Director (QA-II) has informed that inspection of M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi was conducted by Mr. Awais Ahmed, FID DRAP, Karachi on 16-01-2020 and following observation has been mentioned in the inspection report which needs attention of the Registration Board.

"The firm found in violation of DRB decision on segregated section for Psychotropic substance as firm has no segregated section for Psychotropic Products. Psychotropic product "Estazolim" was being manufactured in general OSD section"

As per available record of registered products in PE&R Division, following information has been retrieved regarding registered products of M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi along-with their renewal status.

S/N	Reg. No.	Brand Name	Composition	Manufacturer/ Registration Holder	Remarks of RRR Section
1.	002668	Cerelium 2mg Tablet	Diazepam 2mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Record of renewal submission not available. Evidence for submission of renewal is required to process further.
2.	002669	Cerelium 5mg Tablet	Diazepam 5mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Record of renewal submission not available. Evidence for submission of renewal is required to process further.
3.	007480	Esilgan 1mg Tablet	Estazolam 1mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Transfer of registration from Hakimsons to Helix 20-02-2006. Renewal application received on 11-02-2020.
4.	007481	Esilgan 2mg Tablet	Estazolam 1mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Transfer of registration from Hakimsons to Helix 20-02-2006. Renewal application received on 11-02-2020.
5.	011636	Cereluin Injection	Diazepam 10mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Transfer of registration from Hakimsons to Helix 18-08-2005. Renewal application received on 19-08-2015. Regularization is required for submission of renewal after expiry but within sixty days.

6.	001385	Phenobarbitone Tablet 30mg	Phenobarbitone 30mg	M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi	Transfer of registration from Hakimsons to Helix 06-02-2007. Renewal application received on 27-01-2017 i.e., within time under Rule 27 of Drug L.R&A Rules.

In this regard, Licensing Division has also been requested for confirmation regarding approval status of "Psychotropic Section" of M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E, Karachi. However, response is awaited.

Decision: **Registration Board deferred the case & advised to present comprehensive details on decisions already taken by the Central Licensing Board & Registration Board regarding requirement of segregated facility for psychotropic products along-with the time limits already set to establish segregated facilities.**

Case No.14. Withdrawal of Request For Change In Registration Status of Products From M/s Barrett Hodgson Private Limited Karachi To M/s OBS Pakistan Private Limited Karachi

M/s OBS Pakistan (Pvt) Ltd, C-14, S.I.T.E, Manghopir Road, Karachi applied for change in registration status of following products from M/s Barret Hodgson (Pvt) Limited, Karachi to their name through contract manufacturing at M/s Indus Pharma, Karachi.

1. **Xylocaine Ointment 5%; Reg. No. 023075** (Dy.No. 54 Dated 07-01-2020)
2. **Xylocaine Jelly 2%; Reg. No. 009315** (Dy.No. 53 Dated 07-01-2020)
3. **Xylocaine Topical Solution 4%; Reg. No. 000380** (Dy.No. 55 Dated 07-01-2020)
4. **Xylocaine 2% Injection; Reg. No. 000378** (Dy.No. 64 Dated 07-01-2020)
5. **Xylocaine 2% Solution with Adrenaline; Reg. No. 010112** (Dy.No. 63 Dated 07-01-2020)

However, M/s OBS Pakistan, Karachi has now submitted **"Withdrawal of Product –Xylocaine Range"** on behalf of Aspen Global. In this regard, a letter has also been submitted from Pauline Macdonald- Deputy Chief Operating Officer-Aspen Global Incorporated regarding withdrawal/ discontinuation of commercialization/ marketing of the abovementioned products in Pakistan. Based on Aspen's Instructions, Barrett Hodgson has stopped manufacturing of the products and shall not renew the product licenses with DRAP.

Accordingly, the case has been placed with respect to status of initially submitted applications (Dated 07-01-2020) for transfer/change in registration status of abovementioned products from M/s Barrett Hodgson Private Limited Karachi to M/s OBS Pakistan Private Limited Karachi which shall stand redundant after submission of this withdrawal intimation.

Proceedings of M-296:

The Board was apprised that the abovementioned letter received from Pauline Macdonald-Deputy Chief Operating Officer-Aspen Global Incorporated (regarding withdrawal/ discontinuation of commercialization & marketing of the abovementioned products in Pakistan) states brand names of abovementioned products along-with their registration number. Furthermore, despite of Aspen's Instructions stating "Barrett Hodgson has stopped manufacturing of the products and shall not renew the product licenses with DRAP", M/s Barrett Hodgson, Karachi has changed brand names of abovementioned products from "Xylocaine" to "Xyloaid" as per approval issued vide letter dated 30-09-2019.

Decision: **Keeping in view the abovementioned position, Registration Board referred the case to Legal Affairs Division for their opinion whether discontinuation of commercialization/ marketing of the abovementioned products in Pakistan by Aspen Global requires cancellation of registration of Xylocain Range along-with their registration numbers.**

Case No.15. Issuance of Registration Letter For Products of M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi Approved In 292nd Meeting of Registration Board

Registration Board in its 292nd meeting (held on 1st-2nd October, 2019) approved following products of M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, on contract manufacturing from M/s Surge Laboratories Pvt. Ltd., 10th Km, Faisalabad Road Bikhi, District Sheikhupura as per details given below:

Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, FaisalabadRoad Bikhi, District Sheikhupura Pakistan
Brand Name +Dosage Form + Strength	TEMSUNATE 30mg Injection
Composition	Each vial contains: Artesunate ……30mg
Diary No. Date of R& I & fee	Dy. No 28673 Dated 27-08-2018, Rs. 50,000/- 27-08-2018
Pharmacological Group	Antimalarial
Type of Form	Form-5
Finished product Specification	Firm claim manufacturer specification's
Pack size & Demanded Price	1's & As per PRC
Approval status of product in Reference Regulatory Authorities.	WHO approves injectable artesunate 30mg (WHO Approved formulation)
Me-too status	Gen-M 30mg Injection of M/s Genix Pharma (Pvt) Ltd.
GMP status	M/s Nabiqasim Industries Pvt. Ltd: DML by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP M/s Surge Laboratories Pvt. Ltd: cGMP inspection dated 05-05-2019 shows good level of cGMP compliance of the firm.
Remarks of the Evaluator	
Decision: Approved with innovator's specification	
Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, FaisalabadRoad Bikhi, District Sheikhupura Pakistan
Brand Name +Dosage Form + Strength	TEMSUNATE 120mg Injection
Composition	Each vial contains: Artesunate ……120mg
Diary No. Date of R& I & fee	Dy. No 28675 Dated 27-08-2018, Rs. 50,000/- 27-08-2018
Pharmacological Group	Antimalarial
Type of Form	Form-5
Finished product Specification	Firm claim manufacturer specification's
Pack size & Demanded Price	1's & As per PRC
Approval status of product in Reference Regulatory Authorities.	WHO approves injectable artesunate 120mg (WHO Approved formulation)
Me-too status	Gen-M 120mg Injection of M/s Genix Pharma (Pvt) Ltd.
Remarks of the Evaluator	
Decision: Approved with International pharmacopoeia specification	

Registration letter was with-held for confirmation regarding requisite manufacturing facility of contract manufacturer i.e., M/s Surge Laboratories (Pvt) Ltd., District Sheikhupura. The firm, later on, submitted copy of section approval "grant of additional section-Approval/Decision thereof" for **"Sterile Dry Powder Injectable (General) New Section"** issued by Licensing Division vide letter No. F.1-18/95-Lic (Vol-

III) dated 07-07-2020 in the name of M/s Surge Laboratories (Pvt) Ltd., District Sheikhupura. Accordingly, registration letter has been issued and case is placed for information of the Registration Board.

Decision: Registration Board noted the information.

Case No.16. Revision/ Correction in Formulation of Orazole Gel 2% Approved in 281st Meeting of Registration Board

Registration Board in its 281st meeting (held on 11th- 13th April, 2018) approved following product of M/s Hiranis Pharmaceuticals (Pvt) limited, Plot # E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi as per details given below:

Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt) limited, Plot # E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
Brand Name + Dosage Form + Strength	Orazole Gel 2% w/w
Composition	Each g contains: Miconazole Nitrate……..20mg
Diary No. Date of R& I & fee	Dy. No. 2755, 15-05-2017; Rs.20,000/- (15-05-2017)
Pharmacological Group	Antifungal
Type of Form	Form-5
Finished product Specification	BP
Pack size & Demanded Price	20g & as per PRC
Approval status of product in Reference Regulatory Authorities	Daktarin Oral Gel w/w of M/s Janssen Cilag, UK (MHRA Approved)
Me-too status	Daktacort Gel 2% w/w of M/s Janssen Cilag, Pakistan (Reg. # 009078)
GMP status	Last GMP inspection was conducted on 07-09-2017 and the report concludes satisfactory level of GMP compliance.
Remarks of the Evaluator	● Firm has relevant section as Cream/ Ointment/Gel Section.
Decision: Approved	

Registration letter was with-held for clarification regarding composition as the standard/ reference product approved by RRA & BP monograph for oromucosal gel contains "**Miconazole**" instead of "**Miconazole Nitrate**". Furthrmore, as per British Pharmacopeia, separate monographs are available for "**Miconazole**" & "**Miconazole Nitrate**" which are used in "**Oromucosal Gel**" and "**Cream**" dosage forms, respectively.

The firm has now submitted revised formulation/ label claim along-with fresh fee of Rs.20,000/-

Decision: Registration Board approved the request of M/s Hiranis Pharmaceuticals (Pvt) Limited, Karachi for revision/ correction in formulation of "Orazole Gel 2% w/w" in line with the reference/ standard product approved by Reference Regulatory Authorities. Detail is given as under:

"Each gram contains:
Miconazole……..20mg"

Case No.17. Request For Change In Registration Status of Product(s) From M/s. GlaxoSmithKline Pakistan Ltd, Karachi to M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Jamshoro.

Registration Board in its 291st meeting (held on 02nd – 4th September, 2019) deferred the request of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd [Formerly M/s GSK OTC (Pvt) Ltd.], Petaro Road Jamshoro (DML #000010) for change in registration status of following product from M/s. GlaxoSmithKline Pakistan Ltd, Limited F-268, S.I.T.E, Karachi (DML#000233) to their name through contract manufacturing at GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233) **for confirmation of approval status of required manufacturing facility from Licensing Division**. Detail is as under:

S/N	Reg. No.	Brand Name & Composition of Registered Products	Initial letter of registration with renewal status.	Registration Holder/ Manufacturer	Dy. No. & Date/ Remarks
I	II	III	IV	V	VI
1.	076453	Panadol Forte Suspension Each 5ml contains: Paracetamol……..250mg (BP Specifications)	1- F.No.3-2/2014-Reg-II (M-243) dated 10-07-2014. 2- Last Renewal Application Dated 08-05-2019	GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233)	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) UK MHRA approved formulation.

The firm had provided following documents:-

1. Applications on From-5 along with fee of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) (Duplicate)
2. Copies of initial letter of registration and renewal status.
3. Copy of last GMP inspection report of M/s GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi dated 11-09-2018 and 04-10-2018 (**Good** Level of Compliance).
4. Evidence of approval for change in title from "GSK OTC (Pvt) Ltd Jamshoro" to "M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML #000010)" dated 14-05-2019.
5. NOC from M/s. GlaxoSmithKline Pakistan Ltd, Karachi dated 25-06-2019.
6. Consent from contract manufacturers dated 03-07-2019 and 04-07-2019.

In line with the decision taken by the board, case was referred to Licensing Division for confirmation regarding approval status of requisite manufacturing facility. However, their response is still awaited. Meanwhile, the firm has provided copy of Panel Inspection Report for regularization & renewal of DML as per following details:

a. Panel Inspection Report for renewal of DML for GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233), dated 26,27-03-2019 & 01-04-2019 stating recommendation for renewal of DML and following sections:
   i. Iodex Section/ Ointment Section
   ii. Liquid (General) Section.
   iii. Tablet (General) Section.
   iv. Penicillin Tablet Section

v. Penicillin Capsule Section
vi. Penicillin Dry Suspension Section.

Furthermore, as per copy of panel inspection report conducted for renewal of DML/ grant of additional sections (dated 6th & 7th February, 2017) provided by the firm, M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Jamshoro has 09 sections including "**Liquid/ Syrup Section"**, while the firm has already been granted approval for registration of 08 products on contract manufacturing basis.

Accordingly, the firm was asked to submit clarification for applying contract manufacturing of "Panadol Forte Suspension" at GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi as they have approval for **Liquid/ Syrup Section** at their own facility. Furthermore, the firm was also asked regarding already issued registrations of tablet (general) and Topical dosage forms products on contract manufacturing basis as they hold approval for **"Tablet (General) & Semi solids/ Cream Sections"** at their own facility. In response, the firm has stated that:

"We are in phase of consolidating all our products' manufacturing at our own manufacturing unit i.e. GlaxoSmithKline CHC Pakistan Limited, Petaro Road Jamshoro, through a step wise approach to avoid capacity challenges and shortage in market. Hence, we in first phase had already applied for all liquid preparations manufacture at other facility (Pharmatec) and in next step we will move Panadol Forte Suspension too to our own manufacturing facility. Here, it is important to identify that Panadol Forte is Paracetamol Formulation for kids and in current pandemic of COVID 19 it has major role in managing fever in toddlers while transfer of manufacturing volume require a proper planning to avoid any in market shortage. Therefore, we request DRAP approval under rule 20A 1 (c) and 2 (b) to avoid any shortage in testing time we are facing currently."

Decision: **Registration Board deferred the case and advised M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Jamshoro to submit timelines for provision of necessary manufacturing and testing facility at their own site for these applied and already registered products (date of registration: 17-01-2020 & 07-08-2020) as contract manufacturing under the requested rule 20A, 1(c) of Drug (Licensing, Registering and Advertising) Rules, 1976 is valid for a period not exceeding thirty months.**

Case No.18. Cancellation of Registration of Liquid Infusions of M/s YAS Chemicals, Swabi Having Volumes /Packing Other Than 100ml Glass Bottle.

Registration Board in 294th meeting (held on 9th April, 2020) advised to issue reminder to M/s Yusaf Ali Shah Chemical Industries, Swabi with respect to show cause notice issued to the firm for cancellation of registrations of following Liquid Infusions having volumes other than 100ml glass bottle (i.e., in line with previous decision of Registration Board taken in its 292nd meeting in the light of panel inspection conducted on 20-12-2018 which transpired that the manufacturing facility has capability of producing 100ml infusion in glass bottles/vials only).

Sr.No.	Reg. No.	Brand Name & Composition	Pack Size
1.	016449	Steri-Sol Dextrose 5% + Sodium Chloride 0.9% Injection Contains:- Dextrose Monohydrate…….5% Sodium Chloride …….0.9%	500ml 1000ml
2.	016450	Steri-Sol Ringers Solution Each 500ml contains: Sodium Chloride …….4.3gm Potassium Chloride ……..……0.15gm Calcium Chloride ……0.24gm	500ml
3.	016451	Steri-Sol Dextrose 5% Injection Contains:-	500ml 1000ml

		Dextrose Monohydrate …….5.5gm	
4.	016452	Steri-Sol Sodium Chloride 0.9% Injection Each 100ml contains: Sodium Chloride……0.9gm	1000ml
5.	016454	Steri-Sol Hartmanns Solution Each 500ml contains: Sodium Chloride……..……....3gm Potassium Chloride……..…0.2gm Calcium Chloride……...0.135gm Sodium Lactate……..…....2.65gm	500ml
6.	016455	Steri-Sol Dextrose 5% + Sodium Chloride 0.45% Injection Each 100ml contains:- Dextrose Monohydrate…….5.5gm Sodium Chloride…….….0.45gm	500ml
7.	016456	Steri-Sol Darrows Solution Each 100ml contains:- Sodium Chloride……..……..0.4gm Potassium Chloride……..……..0.26gm Sodium Lactate…….…….0.59gm	500ml
8.	016453	Steri-Sol Metronidazole 0.5% Injection Each 100ml contains: Metronidazole……....0.5gm Sodium Chloride……....0.85gm	100ml PVC Bag.

Accordingly, a reminder was issued to the firm vide letter dated 27-08-2020 to submit a compliance report within 07 days. However, till to date no response has been received.

Decision: Registration Board decided to cancel the registration of above mentioned products due to non-existence of requisite manufacturing facility at M/s Yusaf Ali Shah Chemical Industries, Swabi.

Case No.19. Deferred Products of M/s Hicon Pharmacuticals, Peshawar

Registration Board in its 295th meeting held on 8th-11th June, 2020 deferred the following product of M/s Hicon, Peshawar for submission of complete fee along-with requisite information/documents. Detail is given below:

S. No.	Brand Name / Label Claim	Demanded Pack Size	Demanded Price	Date of Submission	Recommendations of Me-Too Committee Ref. M-238	Remarks
I	II	III	IV	V	VI	VII
1.	Hitaline Syrup Each 5 ml contains:- Terbutaline sulphate…….0.3 mg (Beta-2 adrenergic agonist)	60 ml	As Per SRO	11-5-10	Deferred for submission of correct method of manufacturing and product specification.	RRA status: MHRA (Bricanyl 0.3mg/ml syrup) Me-Too Status: Britanyl 0.3mg/ml Syrup M/s Barret Hodgson, Karachi (R # 044255)

						The firm has submitted fee of Rs.5000/- along with Method of Manufacturing, revised Formulation & Master Formula stating that there is a typographical mistake i.e ***"Each 5ml contains: Terbutaline Sulphate 0.3mg"*** instead of ***"Each ml contains: Terbutaline Sulphate 0.3mg".***

The firm has submitted following documents:

1. Remaining Fee of Rs.15000/- (DS#0508533) dated 19-08-2020 for revision of formulation.
2. Revised form-5, Master Formulation & Outline of manufacturing method:

   Each ml contains:

   Terbutaline Sulphate…….. 0.3mg
3. Last Inspection Report for renewal of DML dated 26-07-2018, wherein the panel has recommended renewal of DML by way of formulation for following sections:
   - Tablet section (General)
   - Tablet Section (General) Antibiotics
   - Liquid Syrup Section (General)

Decision: Registration Board approved the registration of "Hitaline Syrup" with following composition i.e., in line with that of the generic product & reference/ standard product approved by Reference Regulatory Authorities:

"Each ml contains:

Terbutaline Sulphate…….. 0.3mg"

Case No.20. Registration Status of Formulations (Diclofenac Potassium 75mg & 100mg and Famotidine 10mg/5ml) not approved by Reference Regulatory Authorities & Previous Decisions Taken by the Registration Board in its 250th & 258TH Meeting.

Registration Board, in its 288th meeting held on 14th -15th February, 2019 considered the case regarding issuance of show cause notice to registration holders of Diclofenac Potassium 75 and 100mg (Ref. M-258) and current status of court cases filed by different firms against the decision of Registration Board, taken vide its 258th meeting.

Proceedings of M-288:

Registration Board, in its 248th meeting considered the request of M/s Cibex (Pvt.) Ltd Plot No. F-405, S.I.T.E, Karachi wherein it was informed by the firm that have developed their facility for manufacturing of Tablet (General), Capsule (General), Sachet (General), Tablet (General Antibiotics), Liquid Manufacturing, Capsule (General Antibiotics), Dry Syrup (General Antibiotics), Ointment-I (Steriods) and Ointment-II (Non Steriods) located at Plot No. F-405, S.I.T.E, Karachi vide Drug Manufacturing License No.000784.

The firm has requested for transfer of their following registered drugs from M/s Macter International Ltd, Karachi to their name as per following details: -

Sr. No.	Reg. No.	Brand Name(s)	Formulation / Generic Name	Date of Registration	Remarks
1.	027108	Famobex Suspension	Each 5ml contains:- Famotidine….10mg	13-06-2001	The applied formulation is not approved in SRA's
2.	039198	Catafen Tablets 100mg	Each sugar coated tablet contains:- Diclofenac Potassium…….100mg	26-05-2005	Formalities required as per Form -5 are complete

Registration Board in its 248th meeting approved the product at Sr.No.2 and deferred the product at Sr.No.1 for review of formulation.

For product at Sr.No.1 the firm has submitted that the same formulation is freely available, manufactured and marketed by multiple firms in Pakistan. These products are old registered products and were registered prior from the implementation of SRA regime. DRAP has not taken any action to withdraw this product from the market or stop its manufacturing. DRAP has also awarded price increase for same product (Al-Famot) to Ali Industries vide SRO 908(I)/2017 dated 07-09-2017, which demonstrate DRAP's intention to patronize selected companies which unfortunately is discriminating. W.r.t. product at Sr.No.2, the firm has stated that multiple companies are still manufacturing the 75mg and 100mg strength of this molecule without any hindrance from DRAP. Therefore, non issuance of registration is unconstitutional and illegal. . They have requested to grant them registration of above products.

Furthermore, the firm has submitted that "if DRAP issues registration letters of above mentioned two products, we are ready to withdraw the suit (CP Suit No.1545/2017, Cibex vs DRAP & others) filed by us against DRAP and also undertake to stop manufacturing and marketing these two products if other companies are compelled by DRAP to withdraw these products from market."

The case was deferred in 14th meeting of PRVC for deliberation in next meeting. Later on the case was reconsidered in 19th PRVC with following decision taken:

Decision of 19th PRVC:

The Committee deferred the case for presentation before registration board in next meeting with complete background, record and updated status of WP No 1695/2017 filed in Islamabad High Court Islamabad by M/s. Quaper Pharma V/S Federation of Pakistan, in the case of Diclofenec Potassium 100 mg Tablets.

Background

W.r.t above mentioned two formulations, the Registration Board has already taken following decisions:

Sr. No.	Formulation	Ref. Meeting No. of Reg. Board	Decision/Remarks
1.	Famotidine 10mg/5ml Suspension	M-250	***Remarks:*** ***Not approved by reference drug regulatory agencies. Internationally available formulation is dry powder for suspension in the strength of 40 mg/ 5 ml.*** ***(Ref: US FDA)*** **Decision:** i. Applicants shall revise their formulation as per innovator (new registration application with complete fee) within six months if manufacturing facility is approved by CLB.

			ii. For already registered drugs, same procedure as mentioned above (at Sr. No. i) shall be adopted. Otherwise show cause notice shall be issued for de-registration of registered drugs in this formulation. iii. All such application shall be processed on priority basis.
2.	Diclofenac Potassium 75mg & 100mg	M-258	**Decision:** Diclofenac Potassium is not registered in any reference country in dose more than 50mg, thus Registration Board decided to issue show cause notices to manufacturers of Diclofenac Potassium (75 and 100mg) for de-registration of these products.

In this regard, manufactures of Diclofenac Potassium 75mg & 100mg Tablets have already been issued show cause notice including following firms:

S. No	Reg. No.	Firm Name	Name of drug(s) & Composition
1.	021634	M/s Global Pharmaceuticals, Plot no.204-205, Industrial Triangle, Kahuta Road, Islamabad.	Artinil-K Tablets 75mg Each tablet contains: Diclofenac Potassium……..75mg
2.	066670	M/s. Medizan Labs. (Pvt) Ltd. P.No. 313, Industrial Triangle Kahuta Road, Islamabad	Qrelif-75 Tablets Each tablet contains: Diclofenac Potassium…….75mg
3.	027876	M/s. Valor Pharmaceuticals, 124/A Kahuta Road, Industrial Triangle Zone, Islamabad.	Vaclo-Pot Tablets Each tablet contains: Diclofenac Potassium…….75mg
4.	028340	M/s. Robins Pharmaceuticals Industries, 43, Industrial Triangle, Kahutta Road, Islamabad	Dinak Tablets Each tablet contains: Diclofenac Potassium…….75mg
5.	031800	Technovision Pharmaceuticals 295-Industrial Triangle, Kahuta Road.	Ketagesic-75 Tablets Each tablet contains: Diclofenac Potassium…….75mg
6.	037415	Makson Pharmaceuticals Plot No.80-B, Street No.6I-10/3, Industrial Area Islamabad	Makaid-K 75Mg Tablets Each tablet contains: Diclofenac Potassium…….75mg
7.	056845	Webros Pharmaceuticals, Plot # 1, Street # 10, RCCI Industrial Estate, Rawat, Islamabad	Deltaflam Tablets 75mg. Each Tablet Contains :- Diclofenac Potassium.....75mg.
8.	038437	Pearl Pharmaceuticals, Plot No.204, Street No.1, I-10/3, Islamabad	Phlodic-K Each Tablet Contains :- Diclofenac Potassium.....75mg.
9.	024333	Candid Pharmaceutical, Opposite Pasrur Suagr Mills Sialkot Road, Pasru	Kalfen Tablets Each tablet contains:- Diclofenac Potassium.....75mg
10.	047860	M/s. Wise Pharmaceuticals, Plot no.3-A, S-1, RCCI Industrial Estate, Rawat, Islamabad.	Achex-75mg Tablets Each film coated tablet contains: Diclofenac Potassium.....75mg
11.	049385	M/s shawan Pharmaceuticals, Plot no.37, road NS-1, National Industrial Zone Rawat Islamabad	Lofen Tablets Each tablet contains: Diclofenac Potassium.....75mg

12.	043655	Miracle Pharmaceuticals (Pvt.) Ltd. Pharmaceuticals (Pvt) Ltd	Marinac-P 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
13.	043987	M/s Neomedix Pharmaceuticals, Islamabad	Neofenik- 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
14.	037574	M/s Vision Pharmaceuticals, Islamabad	Deflam 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
15.	038553	M/s Glitz Pharmaceuticals, Islamabad	Glif-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
16.	050019	M/s Caraway Pharmaceuticals, Islamabad	Carafenac-P 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
17.	050107	M/s Harrison Pharmaceuticals, Islamabad	Diclokam-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
18.	050953	M/s Leads Pharma, Islamabad	Diclosoft-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
19.	052552	M/s Panacea Pharmaceuticals, Islamabad	Tasilex 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
20.	052727	M/s Paramount Pharmaceuticals, Islamabad	Ronset SRTablets Each tablet contains:- Diclofenac Potassium 75mg

Status of WP No 1695/2017

M/s. Quaper Pharmaceuticals (Pvt) Limited, Sargodha has filed a Writ Petition in Islamabad High Court Islamabad v/s Federation of Pakistan, Drugs Registration Board etc against issuance of show cause notice in the case of Diclofenec Potassium 75mg Tablets. The case was heard on 30-05-2017and adjourned.

Decision of M-288: **Registration Board decided that all registration holders of "Diclofenac Potassium 75mg & 100mg" shall be called for personal hearing.**

Current Status of WP No 1695/2017 (Ref. M-295):

The Islamabad High Court, Islamabad dismissed the application of M/s. Quper Pharma, Sargodha vide its orders dated 29-01-2020 being without merit. Registration Board in its 295th meeting deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to all the firms who have registration of Diclofenac Potassium 75mg & 100mg in forthcoming meeting of Registration Board.

Decision taken by DRAP's Authority in its 70th meeting held on 05-09-2019:

For formulations containing "drugs" which were previously registered by the Registration Board and have proof of availability and prescription of last 10 years but are not available in the Reference Regulatory Authorities shall continue to be considered/ registered as drugs until and unless withdrawn on Safety, Efficacy and Quality reasons.

Draft List of Registered Products Containing Diclofenac Potassium 75mg & 100mg

Sr.No.	Reg. No.	Brand Name & Composition	Reg. Holder

1.	023973	Fen-K SR Tablet 100mg Diclofenac Potassium…100mg	Pakheim International Pharma (Pvt) Ltd., 28 Km Ferozepur Road Lahore., Lahore
2.	030960	Artimov-K Tablets 100mg Diclofenac Potassium …..100mg	Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi
3.	031178	Mediflam SR 100mg Tablets Diclofenac Potassium……100mg	Mediceena Pharma (Pvt) Ltd., 27 Km Raiwind Road Lahore, Lahore
4.	038450	Kaldic Tablet Each tablet contains:- Diclofenac Potassium 100mg	Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore., Lahore
5.	039198	Catafen 100 Tablets Diclofenac Potassium…..100mg	
6.	039800	Noafilm Tablet 100mg DiclofenacPotassium…...100mg	Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi. , Karachi
7.	042985	Movom-P Capsule 100mg DiclofenacPotassium (enteric coated granules)…100mg	Nenza Pharmaceuticals (Pvt) Ltd., 33-A Hayatabad Industrial Estate Peshawar. , Peshawar
8.	047294	Dic-P 100mg Tablets Each tablet contains Diclofenac Potassium……100mg	Uni-Tech Pharmaceuticals (Pvt) Ltd., Plot No. 4/116 Sector 21 Korangi Industrial Area Karachi. , Karachi
9.	052727	Ronset SR Tablets. Diclofenac Potassium……100mg	Paramount Pharmaceuticals, 36 Industrial Triangle, Kahuta Road Islamabad., Islamabad
10.	053260	Sustiva 100mg Tablet Diclofenac Potassium ….. ……100mg	Mediate Pharmaceutical (Pvt) Ltd., Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi., Karachi
11.	054325	Fapa 100mg SR Tablet Diclofenac Potassium…….100mg	Caylex Pharmaceuticals (Pvt) Ltd., 27-Km Mian Raiwind Road Lahore., Lahore
12.	054918	Artinil-K SR 100mg Tablet Each tablet contains:- Diclofenac Potassium 100mg	Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad., Islamabad
13.	013758	Diclokon-100 Sugar Coated Tablet Each tablet contains:- Diclofenac…… 100mg	
14.	055109	Dyfe-P 100mg SR Tablet DiclofenacPotassium……100 mg	Safe Pharmaceuticals (Pvt) Ltd., Plot No C-I, 20, Sector 6-B, North Karachi Industrial Area, Karachi, Karachi
15.	058147	Zulfenec –P 100mg Tablet Diclofenac Potassium…….100 mg	Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39 Sector 15 Korangi Industries Area Karachi., Karachi

16.	058263	Velflex 100mg Tablet Diclofenac Potassium ……100 mg	Ray Pharma (Pvt) Ltd., S-58 S.I.T.E. Karachi, Karachi
17.	060292	Difene 100mg SR Capsule Diclofenac Potassium Enteric Coated Pellets eq. to Diclofenac Potassium…….100mg	Aries Pharmaceuticals (Pvt) Ltd., 1-W Industrial Estate Hayatabad Peshawar., Peshawar
18.	060366	Harrifan-K 100mg Tablet Diclofenac Potassium….100mg	Harrison Pharmaceuticals, 10-Km Lahore Road Sargodha. , Sargodha
19.	063176	Mobil-K 100mg Tablets Each tablet contains:- Diclofenac Potassium 100mg	Davis Pharmaceutical Laboratories , Plot No. 121 Industrial Triangle Kahuta Road Islamabad., Islamabad
20.	064026	DP-Med 100mg Tablet Diclofenac Potassium.…100mg	Medicraft Pharmaceuticals (Pvt) Ltd., 126-B Industrial Estate Hayatabad, Peshawar., Peshawar
21.	064198	Diclosaf-P SR 100mg Tablets Diclofenac Potassium…….100mg	SAAAF Pharmaceutical Industries , Plot No. 15 Nowshera Industial Estate Risalpur., Risalpur
22.	064842	Declam Tablet 100mg Diclofenac Potassium……100mg	NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km Ferozepur Road Lahore, Lahore
23.	065135	Ronac Tablet Each tablet contains:- Diclofenac Potassium 100mg	Rogen Pharmaceuticals, Plot No. 30 S-4 National Industrial Zone Rawat Islamabad, Islamabad
24.	065546	Theradic-P Tablet 100mg Diclofenac Potassium….100mg	Theramed Pharmaceuticals (Pvt) Ltd., 45-Km Multan Road Lahore., Lahore
25.	073273	Anti-Pain 100mg Capsule Diclofenac Potassium Pellets equivalent to Diclofenac Potassium……100mg	Medicraft Pharmaceuticals (Pvt) Ltd., 126-B Industrial Estate Hayatabad, Peshawar., Peshawar
26.	021634	Artinil-K 75mg Tablet Diclofenac Potassium..75mg	Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad., Islamabad
27.	022543	Maxit 75mg Tablet Diclofenac Potassium… 75 mg	Hilton Pharma (Pvt) Ltd., Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi. , Karachi
28.	023811	Ardi-K Tablet Diclofenac Potassium…..75mg	English Pharmaceutical Industries, Indus Link Katarband Road Thokar Niaz Beg, Multan Road Lahore., Lahore
29.	023822	Klic-F tablet Diclofenac Potassium……75mg	Tabros Pharma (Pvt) Ltd., Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi., Karachi
30.	024049	Rheumatin-K Tablet Diclofenac Potassium…75mg	Siza International (Pvt) Ltd., 18-Km Main Ferozepur Road Lahore, Lahore

31.	024273	Antiflam Tabelts Each tablet contains:- Diclofenac Potassium…..75mg	Wilshire Laboratories (Pvt) Ltd ., 124/1 Industial Estate Kot Lakhpat Lahore. , Lahore
32.	024333	Kalfen Tablet 75mg Diclofenac Potassium...75mg	Candid Pharmaceuticals, Opp Pasrur Sugar Mills Sialkot Road, Pasrur., Pasrur
33.	028340	Biscot Tablet Diclofenac Potassium……..75mg	
34.	028866	Inflaban 75 Tablet Diclofenac Potassium……..…75mg	Medera Pharmaceuticals (Pvt) Ltd., 249-A Industrial Triangle Kahuta Road Islamabad., Islamabad
35.	030959	Artimov-K Tablets 75mg Diclofenac Potassium …..75mg	Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi
36.	031128	Beflam Tablets 75mg Diclofenac Potassium ….75mg	Batala Pharmaceuticals, 23/B Small Industrial Estate No. 2 Near Wapda Town, Khiali Bypass Gujranwala, Gujranwala
37.	031800	Ketagesic-75 Tablet Diclofenac Potassium……75mg	
38.	032086	Tonek Tablet 75mg Diclofenac Potassium …75mg	Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar., Peshawar
39.	032102	Dicfin 75mg Tablets Each tablet contains:- Diclofenac Potassium 75mg	Dr. Raza Pharma, Road B-4 P.No 44-C Industrial Estate, Jamrud Road, Peshawar., Peshawar
40.	035988	Quikrel 75mg Tablet Each tablet contains:- Diclofenac Potassium 75mg	Z-Jans Pharmaceutical (Pvt) Ltd., 148-A Industrial Estate Hayatabad Peshawar. , Peshawar
41.	036326	Aldal Tablets Diclofenac Potassium…75mg	Alson Pharmaceutical, 169, Road No. 7-B, Industrial Estate Hayatabad Peshawar., Peshawar
42.	036727	Confenac-K Tablets Diclofenac Potassium…….75mg	Convell Laboratories, Saidu Sharif Swat, Swat
43.	036772	Pofen 75mg Tablets Diclofenac Potassium……..75mg	Fozan Pharmaceticals Industries (Pvt) Ltd., 36-A Hayatabad Industrial Estate Peshawar., Peshawar
44.	036815	Dic-P 75mg Tablets Diclofenic Potassium…….75mg	Shaheen Pharmaceuticals, 3-Km Murghzar Road Saidu Sharif Swat., Swat
45.	037197	Ardic K Tablets Diclofenac Potassium……75mg	Wilshire Laboratories (Pvt) Ltd ., 124/1 Industial Estate Kot Lakhpat Lahore. , Lahore
46.	037415	Makaid-K 75mg Tablets Diclofenac Potassium…75mg	
47.	037574	Diclovis-K 75Mg Tablets Each tablet contains	Vision Pharmaceuticals, Plot No. 22-23 Industrial Triangle

		Diclofenac Potassium……..75mg	Kahuta Road Islamabad, Islamabad
48.	037849	Phenpal Capsule Each capsule contains:- Diclofenac Potassium 75mg	Alson Pharmaceutical, 169, Road No. 7-B, Industrial Estate Hayatabad Peshawar., Peshawar
49.	037887	Diclovel Tablets Diclofenac Potassium…..75mg	Convell Laboratories, Saidu Sharif Swat, Swat
50.	037975	Dicomak 75mg Tablets Diclofenac Potassium…75mg	
51.	038016	Dicloned-k 75mg tablet Diclofenac Potassium USP……..75mg	Nenza Pharmaceuticals (Pvt) Ltd., 33-A Hayatabad Industrial Estate Peshawar. , Peshawar
52.	038169	Synoflam- 75Mg Tablets Diclofenac PotassiumUSP…..75mg	Fedro Pharmaceutical Labs (Pvt) Ltd., 149-Industrial Estate Jamrud Road Peshawar., Peshawar
53.	038342	Irozee-F Tablet Each tablet contains:- Diclofenac Potassium 75mg	
54.	038437	Phlodic-K Tablet Each tablet contains:- Diclofenac Potassium 75mg	Pearl Pharmaceuticals, Plot No 204 Street No. 1 I-10/3 Industrial Area Islamabad., Islamabad
55.	038553	Glift-K 75mg Tablet Each tablet contains:- Diclofenac Potassium 75mg	Glitz Pharma, Plot No 265 Industrial Triangle Kahuta Road Islamadad. , Islamabad
56.	040186	Ura 400mg Tablet DiclofenacPotassium…….75mg	Rasco Pharma (Pvt) Ltd., 5.5 Km Raiwind Road Ali Razabad Lahore., Lahore
57.	041483	Getab tablet Diclofenic Potassium…… 75mg	Hicon Pharmaceuticals, 131-Industrial Estate Hayatabad Peshawar., Peshawar
58.	041945	Mobil K 75mg Tablet Diclofenac Potassium…….75 mg	Davis Pharmaceutical Laboratories , Plot No. 121 Industrial Triangle Kahuta Road Islamabad., Islamabad
59.	042123	Noafilm-75 Tablet 75mg Diclofenac Potassium……75mg (Anti-rheumaticsystemic)	Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi. , Karachi
60.	042483	Medic-P 75mg Tablets Diclofenac Potassium…...…75mg	Medicure Laboratories, Plot No. F./109 Behind Karachi Polytechnic Hub River Road SITE Karachi., Karachi
61.	042984	Movom-P cap 75mg Diclofenac Potassium (enteric coated granules)…75mg	Nenza Pharmaceuticals (Pvt) Ltd., 33-A Hayatabad Industrial Estate Peshawar. , Peshawar
62.	043605	Declam Tablets 75mg Diclofenac Potassium(B.P)……75mg	NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km Ferozepur Road Lahore, Lahore

63.	043655	Marinac-P 75 tablet Each tablet contains:- Diclofenac Potassium 75mg	Miracle Pharmaceuticals (Pvt) Ltd., Plot No-8 Street No-5 National Industrial Zone Rawat, Islamabad, Islamabad
64.	043908	Digam Tablets 75mg Diclofenac Potassium……75mg.	Navegal Laboratories, Plot No. 41/1-A-2 Phase-I Industrial Estate Hattar Peshawar,, Peshawar
65.	046175	Reform Capsules 75mg. Diclofenac Potassium…….75mg	
66.	046202	Kaymax Tablet Diclofenac Potassium…….75mg. (B.P)	Quaper (Pvt) Ltd., 26-A S.I.E. Lahore Road Sargodha., Sargodha
67.	046215	Brisc Tablets 75mg. Diclofenac Potassium……75mg. (B.P)	Envoy Pharmaceuticals (Pvt) Ltd., 27-Km Multan Road Maraka Lahore , Lahore
68.	046319	Diclopot 75mg tablet Diclofenac Potassium……..75mg.	
69.	046893	Feflam-75 Tablets. Diclofenac Potassium …75mg.	Festal Laboratories, Jinnah Industries Link Kattar Band Road Thokar Niaz Baig Lahore., Lahore
70.	047860	Achex Tablet Each tablet contains:- Diclofenac Potassium 75mg	Wise Pharmaceuticals, Plot No. 3-A Street S-1 National Industrial Zone, Rawat Islamabad, Islamabad
71.	048383	Deflam Tablet 75mg Diclofenac Potassium ……75mg. (B.P)	CCL Pharmaceuticals (Pvt) Ltd., 62 Industrial Estate Kot Lakhpat Lahore, Lahore
72.	049013	Caveron Tablet 75mg Each tablet contains:- Diclofenac Potassium 75mg	FYNK Pharmaceuticals, 19-Km Ferozepur Road G.T. Road Kala shah Kaku Lahore. , Lahore
73.	049385	Lofen 75mg Tablet Diclofenac Potassium……..75mg. (B.P Specs)	Shawan Pharmaceuticals, Plot No. 37 Road NS-1 National Industrial Zone Rawat Rawalpindi., Rawalpindi
74.	049839	D-K Tablet 75mg Diclofenac Potassium ……75mg. (USP Specs)	Ferroza International Pharmaceuticals (Pvt) Ltd., 33-Km Ferozepur Road Lahore., Lahore
75.	050019	Carafenac-P Tablets 75mg. Diclofenac Potassium ……..75mg. (USP Specs)	Caraway Pharmaceuticals, Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat Islamabad., Islamabad
76.	050107	Diclokam-K Tablets 75mg. Diclofenac Potassium …….75mg. (USP Specs)	Harrison Pharmaceuticals, 10-Km Lahore Road Sargodha. , Sargodha
77.	050330	Kemipan Plus Tablet Diclofenac Potassium……75mg	Alkemy Pharmaceutical Laboratories (Pvt) Ltd., P-9 SITE Hyderabad., Hyderabad
78.	050953	Diclosoft- K Tablets 75mg. Diclofenac Potassium…….75mg. (B.P Specs)	Leads Pharma (Pvt) Ltd., Plot No. 81-A Street No. 6 I-10/3 Islamabad., Islamabad

79.	051172	Engrol 75mg Capsules. Diclofenac Potassium…….75mg. (BP Specs)	English Pharmaceutical Industries, Indus Link Katarband Road Thokar Niaz Beg, Multan Road Lahore., Lahore
80.	052438	Dicsium Tablets. Diclofenac Potassium……..75mg. (B.P Specs)	Evergreen Pharmaceuticals , 69-70/B Main Glaxo Town Industrial Estate 20Km Ferozepur Road Lahore, Lahore
81.	052552	Tasilex Tablets 75mg Diclofenac Potassium…….75mg.	Panacea Pharmaceuticals, Plot No.4 Street No.S-6 National Industrial Zone Rawat Islamabad., Islamabad
82.	052707	Unifin Tablet 75mg Each tablet contains:- Diclofenac Potassium 75mg	Unison Chemical Works, 15 Km Raiwind Road Lahore., Lahore
83.	052803	Tasium Capsule 75mg. Diclofenac Potassium (as enteric coated Pellets)……75mg.	Panacea Pharmaceuticals, Plot No.4 Street No.S-6 National Industrial Zone Rawat Islamabad., Islamabad
84.	054195	Frendic-P Tablet 75mg Diclofenac Potassium…….75mg (USP Specs)	Friends Pharma (Pvt) Ltd., 31-Km Ferozepur Road Lahore., Lahore
85.	054273	Muskel 75mg Tablets Diclofenac Potassium……..75mg (USP Specs)	
86.	054527	Difene 75mg Capsule Diclofenac Potassium enteric coated pellets equivalent to …….75mg	Aries Pharmaceuticals (Pvt) Ltd., 1-W Industrial Estate Hayatabad Peshawar., Peshawar
87.	054665	Dipot-K Tablet Each tablet contains:- Diclofenac Potassium 75mg	Tas Pharma (Pvt) Ltd., 209 Sehala Triangle Kahuta Road Islamabad., Islamabad
88.	054702	D-Fine P 75mg Tablet Diclofenac Potassium ……75mg	Alliance Pharmaceuticals (Pvt) Ltd., 112-A Hayatabad Industrial Estate Peshawar, Peshawar
89.	055108	Dyfe-P 75mg Tablet Diclofenac Potassium…75mg	Safe Pharmaceuticals (Pvt) Ltd., Plot No C-I, 20, Sector 6-B, North Karachi Industrial Area, Karachi, Karachi
90.	055997	Qufen -K 75mg Tablet Diclofenac Potassium……..….75mg	High-Q Pharmaceuticals, Plot No. 224 Sector 23 Korangi Industrial Area Karachi , Karachi
91.	056183	Potafin Tablet Each tablet contains:- Diclofenac Potassium 75mg	Goodman Laboratories, Plot No.5 St: No. S-5 National Industrial Zone Rawat Islamabad., Islamabad
92.	056250	Dipolive 75mg Tablet Each tablet contains:- Diclofenac Potassium 75mg	Olive Laboratories, Plot No.52-S-6 National Industrial Zone Rawat Rawalpindi., Rawalpindi

93.	056377	Dlf-K Tablet Each tablet contains:- Diclofenac Potassium 75mg	Crown Pharmaceuticals, 286 Kahuta Industrial Triangle Islamabad., Islamabad
94.	056529	Pofac 75mg tablet Diclofenac Potassium……75mg	Wnsfield Pharmaceuticals, Plot No. 122 Block-A Phase-V Industrial Estate Hattar. , Hattar
95.	056701	Volden Fort K 75mg Tablet Each tablet contains:- Diclofenac Potassium 75mg	Rotex Pharma (Pvt) Ltd., Plot No. 206-207 Industrial Triangle Khuta Road Islamabad, Islamabad
96.	056720	Dilo-K 75mg Capsule Diclofenac Potassium75mg	Farm Aid Group, Plot No. 3/2 Hattar Industrial Area Hattar., Hattar
97.	056845	Detaflam Tablet 75mg Diclofenac Potassium.....75mg.	Webros Pharmaceuticals, Plot No. 1 Street No. 10 National Industrial Zone Rawat Islamabad. , Islamabad
98.	056977	Olitass Capsule Each capsule contains:- Diclofenac Potassium 75mg	Olive Laboratories, Plot No.52-S-6 National Industrial Zone Rawat Rawalpindi., Rawalpindi
99.	057517	Lyon Tablet Diclofenac Potassium…75mg.	Alfalah Pharma (Pvt) Ltd., 12-Km, Sheikhupura Road, Lahore. , Lahore
100.	057612	Detran-P 75mg Tablet Diclofenac Potassium…..75mg	Sunshine Pharmaceuticals, Emanabad, G.T. Road, Gujranwala, Gujranwala
101.	057662	K-Lam Tablets 75mg Diclofenac Potassium …..75mg	DrugPharm (Pvt) Ltd., 28-Km, Sheikhupura Road, Lahore, Lahore
102.	057784	Fareop 75 mg Tablet Diclofenac Potasium……75mg	
103.	057985	Painogin 75mg Tablet DiclofenacPotassium…...75mg	Zanctok Pharmaceutical Laboratories, F/5 SITE Hyderabad., Hyderabad
104.	058146	Zulfenec –P 75mg Tablet Diclofenac Potassium……..75 mg	Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39 Sector 15 Korangi Industries Area Karachi., Karachi
105.	058262	Velflex 75 mg tablet Diclofenac Potassium …….75 mg	Ray Pharma (Pvt) Ltd., S-58 S.I.T.E. Karachi, Karachi
106.	058318	Hasten 75mg Tablet Diclofenac Potassium…..…...75 mg	
107.	058404	Corom-P 75mg Tablet Diclofenac Potassium ……...75 mg	Zephyr Pharmatec (Pvt) Ltd., Plot No. A-39 S.I.T.E. II Super Highway Karachi., Karachi
108.	058420	Eplopot Tablet Diclofenac Potassium …..75 mg	E-Pharm Laboratories, A-40 S.I.T.E Super Highway North Karachi, Karachi
109.	059535	D-Fenac Tablets Each tablet contains Diclofenac Potassium…….75mg	Medley Pharmaceuticals, 41/A Punjab Small Industries Estate Jhang Bahtar Road Wah Cantt., Wah Cantonment

110.	059625	Nostif-K Tablet Diclofenac Potassium…..75mg	Axis Pharmaceuticals , 3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad., Faisalabad
111.	059883	Zofen-K Tablets 75mg Each tablet contains:- Diclofenac Potassium…75mg	Harmann Pharmaceutical Laboratories (Pvt) Ltd., 16-Km Multan Road Lahore. , Lahore
112.	059971	Reuqin-75mg Tablet Diclofenac Potassium….75mg	Qintar Pharmaceuticals, 14-A Small Industrial Estate Lahore Road Sargodha., Sargodha
113.	060445	Relic Tablet 75mg Diclofenac Potassium…..75mg	Brand Pharma International,, K-105, Super Highway, Phase-II, S.I.T.E, Karachi, , Pakistan, Pakistan
114.	060923	Flexura 75mg Tablet Diclofenac Potassium…….75mg	Fassgen Pharmaceuticals, Plot No. 67/1 Block-A Phase-III Industrial Estate Hattar. , Hattar
115.	060965	Diclowan-P 75mg Tablet Diclofenac Potassium…75mg	Swan Pharmaceutical (Pvt) Ltd., 11-E Industrial Triangle Kahuta Road Islamabad. , Islamabad
116.	061515	Blif-B Tablet Each tablet contains:- Diclofenac potassium … 75 mg	Brand Pharma International,, K-105, Super Highway, Phase-II, S.I.T.E, Karachi, , Pakistan, Pakistan
117.	061574	Dicsod-K Tablet Each tablet contains:- Diclofenac potassium … 75 mg	Medicaids (Pvt) Ltd., Plot No 10 Sector 37 Korangi Industrial Area Karachi., Karachi
118.	062476	Kaynac Capsule 75mg Diclofenac Potassium Pellets Eq. to Diclofenac Potassium …75mg	Hoover Pharmaceuticals (Pvt) Ltd., Plot No.16 Zain Park Industrial Area Saggain By Pass Road Lahore., Lahore
119.	062591	Diclotal K Tablet 75mg Diclofenac Potassium….75mg	Berlex Lab. International, 10-Km Nangshah Chowk Karachi Road Multan, Multan
120.	062636	Diclofil P Tablet Diclofenac Potassium….75mg	Murfy Pharmaceuticals (Pvt) Ltd., 8-Km Raiwind Road Lahore., Lahore
121.	062985	Diclosaf-P 75mg Tablets Diclofenac Potassium…..75mg	SAAAF Pharmaceutical Industries , Plot No. 15 Nowshera Industial Estate Risalpur., Risalpur
122.	063038	Arthopot Capsule Diclofenac Potassium…..75mg	Gillman Pharmaceuticals, Plot No. 41/2-A Phase-I & II Industrial Estate Hattar. , Hattar
123.	063262	Diclotus-K Tablet Each tablet contains:- Diclofenac Potassium 75mg	Lotus Pharmaceutials (Pvt) Ltd. , Plot No.118-A Street No. 8, I-10/3 Industrial Area Islamabad. , Islamabad

124.	064022	Anti-Pain 75mg Capsule Diclofenac Potassium Pellets equivalent to Diclofenac Potassium……..…..75mg	Medicraft Pharmaceuticals (Pvt) Ltd., 126-B Industrial Estate Hayatabad, Peshawar., Peshawar
125.	064588	Daikin Tablets 75mg Diclofenac potassium….75mg	3S Pharmaceuticals (Pvt) Ltd,, 5km Off Raiwind Manga Road, Lahore, , Pakistan, Pakistan
126.	064791	Pointer 75 Capsule Diclofenac Potassium (Pellets)…..75mg	M/s Shrooq Pharmaceuticals (Pvt) Ltd,, 21 Km Ferozpur Road,
127.	065126	Relpain Tablet Each tablet contains:- Diclofenac Potassium 75mg	Well & Well Pharma (Pvt) Ltd., Plot No.7 Street S-8 National Industrial Zone RCCI Rawat Islamabad., Islamabad
128.	065134	Ronac Tablet Each tablet contains:- Diclofenac Potassium 75mg	Rogen Pharmaceuticals, Plot No. 30 S-4 National Industrial Zone Rawat Islamabad, Islamabad
129.	065195	Biodic-P Tablet Each tablet contains:- Diclofenac Potassium 75mg	Biorex Pharmaceuticals, Plot No.292 Industrial Triangle Kahuta Road Islamabad., Islamabad
130.	065234	Linofenac-P 75mg Tablet Each tablet contains:- Diclofenac Potassium 75mg	Linear Pharma, Plot No. 18 S. No. S-4 National Industrial Zone (RCCI) Rawat Islamabad., Islamabad
131.	066480	Frisky Tablet Each tablet contains:- Diclofenac Potassium 75mg	Crest Pharmaceuticals, Plot No. 43 Industrial Triangle Kahuta Road Islamabad., Islamabad
132.	066670	Qrelif-75 Tablets Diclofenac Potassium…75 mg	Medizan Laboratories (Pvt) Ltd., Plot No 313 Industrial Triangle Kahuta Road Islamabad., Islamabad
133.	066886	Regopyrin Tablet 75mg Diclofenac Potassium …..75 mg	Regent Laboratories, C-20 SITE Super Highway Karachi. , Karachi
134.	068239	Naveflam Capsules 75mg. Diclofenac Potassium….75mg	Navegal Laboratories, Plot No. 41/1-A-2 Phase-I Industrial Estate Hattar Peshawar,, Peshawar
135.	068326	Dolwel 75mg Tablet Diclofenac Potassium……75mg	WelMark Pharmaceuticals, Plot No. 122 Block-B Phase-V Industrial Estate Hattar. , Hattar
136.	068362	Rxoflam Tablets 75mg. Diclofenac Potassium……75mg	Healer Laboratories (Pvt) Ltd., 96/102-C SIE Kohat Road Peshawar., Peshawar
137.	068456	Volmed-K Capsule Diclofenac Potassium……75mg	Meditech Pharmaceuticals, 15-D Industrial Estate, Jamrud Road, Peshawar, , Pakistan, Pakistan
138.	069004	Kenac Tablet 75mg Diclofenac Potassium ….75mg	Medisave Pharmaceuticals, Plot No.578-579 Sundar

			Industrial Estate Lahore., Lahore
139.	069281	Zainex 75mg tablet Diclofenac Potassium…….75mg	Sapient Pharma, 123-S Industrial Area Kot Lakhpat Lahore., Lahore
140.	069285	Denum K Tablets Diclofenac Potassium……..75mg	Irza Pharma (Pvt) Ltd., 10.2-Km Lahore Sheikhupura Road P.O Kot Abdul Malik District Sheikhupura., Sheikhupura
141.	073586	Defenac 75mg Capsule Each capsule contains Diclofenac Potassium: 75mg	Mediate Pharmaceutical (Pvt) Ltd., Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi., Karachi
142.	074198	Peflam Tablet Diclofenac Potassium……75mg	Arsons Pharmaceutical Industries (Pvt) Ltd., 22-Km Multan Road Off 2.5-KM Defence Road, Lahore., Lahore
143.	074501	Caldic 75mg Tablet Diclofenac Potassium….75mg	Caliph Pharmaceuticals (Pvt) Ltd., Plot No. 17 Industrial Estate Risalpur, Risalpur
144.	074597	Nexfen Tablets 75 mg. Diclofenac Potassium……..75 mg	Libra (Pvt) Ltd., 77 Industrial Estate Hayatabad Peshawar., Peshawar
145.	076892	Dicgesic-K Tablets 75 mg Each film coated tablet contains Diclofenac Potassium: 75mg	Alen Pharmaceuticals (Pvt) Ltd., 138 Nowshera Industrial Estate, Risalpur., Risalpur
146.	078831	VALRON-P 75 Tablets Each film coated tablet contains Diclofenac Potassium: 75mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore
147.	077028	Basocap -75mg Capsule Each capsule contains Diclofenac Potassium (Pellets): 75mg	Basel Pharmaceuticals , 227-Phase-II Multan Industrial Estate Multan, Multan
148.	021577	Keygesic Tablet 75mg Each tablet contains Diclofenac Potassium: 75mg	Benson Pharmaceuticals, Plot No.119 Street No.8, I-10/3 Industrial Area Islamabad. , Islamabad

List of Registered Products Containing Famotidine 10mg/5ml

S/N	Reg. No.	Brand Name & Composition	Manufacturer
1.	024255	Acicon Suspension Each 5ml contains:- Famotidine USP…..10mg	Barrett Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi-75700 , , , ,
2.	025037	Peptiban Suspension Famotidine.....10mg	Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad., , Pakistan, Pakistan
3.	025149	Fadiphine Suspension Famotidine.....10mg	Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad., , Pakistan, Pakistan
4.	025469	Capcid Suspension Each 5Ml Contains:- Famotidine.....10mg	Bloom Pharmaceuticals (Pvt) Ltd, Plot No30, Hattar Ind

			Estate, Phase I & II, Hattar , , , ,
5.	025565	Reducid Suspension Famotidine.....10mg	Platinum Pharmaceuticals (Pvt) Ltd, A-20, North Western Industrial Zone, Bin Qasim, Karachi, , , ,
6.	025568	Ulcenil Suspneion Each 5Ml Contains:- Famotidine....10mg	Siza International (Pvt) Ltd, 18 KM, Main Ferozepur Road, Lahore-53000, , , ,
7.	027108	Famobex Suspension Each 5Ml Contains:- Famotidine…..10.000mg	Macter International (Pvt) Ltd, , F-216, S.I.T.E, Karachi
8.	027115	Famorex Suspension Each 5Ml Contains:- Famotidine……..10mg	Mediceena Pharma (Pvt) Ltd, , 27-K.M, Raiwind Road, Lahore
9.	027709	Zepsin Suspension Famotidine……..10mg	Cirin Pharmaceuticals,, 32/2A, Phase III, Industrial Estate, Hattar. Manufactured by M/s. Bloom Pharmaceutical, Hattar.
10.	027723	Peprax Suspension Famotidine….10mg	Umersons Laboratories,, 467, Industrial Area,Sector I/9, Islamabad
11.	028254	Famoscot Oral Suspension 10mg Famotidine……10 mg	Scotmann Pharmaceuticals, 5D, I-10/3 Industrial Area, Islamabad
12.	030082	Nulcer Suspension Famotidine …….10mg	Brookes Pharmaceutical Labs, (Pak) Ltd,, 58/15, Korangi Industrial Area,, , Pakistan, Pakistan
13.	030124	Recid Syp Famotidine…..10mg	Regent Laboratories,, Plot No. C-20 S.I.T.E,, , Pakistan, Pakistan
14.	030273	Cantil Suspension Famotidine……10mg	Helicon Pharmaceutek, Pakistan (Pvt) Ltd,, Model Town Road,Faisalabad, , ,
15.	031233	Peprid Suspension Famotidine …….10mg	Helix Pharma (Pvt) Ltd,, A/56, S.I.T.E.,, , Karachi,
16.	031646	Capcid Suspension Famotidine…….10mg	Olive Laboratories,, Plot # 52-S6, National Industrial Zone , , Pakistan, Pakistan
17.	031771	Fadin Suspension Famotidine ……10mg	Zeb Laboratories, (Pvt) Ltd,, Link Rai-Wind Road, Nisar Abad,, , Pakistan, Pakistan
18.	033340	Fagastril Syrup Famotidine…….10mg	Gray's Pharma, Islamabd, , ,
19.	033684	Acidrol Suspension Famotidine ……10mg	Medisearch Pharmacal, Lahore, , Pakistan, Pakistan
20.	033704	Neofam Suspension Famotidine……..10mg	Neomedix , Plot No.5, N-5 National Industrial Zone Rawat (Islamabad), , Pakistan, Pakistan
21.	033996	Pepton Suspension Famotidine…..10mg	Paramount Pharma,Islamabad, 36,Industrial Triangle Kahuta Road,Islamabad, , Pakistan, Pakistan

22.	034789	Gastridine Suspension Famotidine……..10mg	Unicorn Pharma , E-30, Sector 15, Korangi Industrial Area, Karachi-74902, , Pakistan, Pakistan
23.	035275	Ge Pep Suspension Each 5ml contains:- Famotidine 10mg	Akson Pharmaceuticals Co. (Pvt.) Ltd.
24.	037994	Famotop Suspension Famotidine…….10mg	Xenon Pahrma, Lahore.
25.	038876	Neutidin Suspension 10mg/5ml Famotidine…….10mg	Neutro Pharma (Pvt) Ltd, 9.5Km,Sheikhupura Lahore, , Pakistan, Pakistan
26.	040312	Fomen Suspension 10mg Famotidine…..10mg	Shrooq Pharmaceutical (Pvt) Ltd, , 21-KM, Feroze Pur Road, Lahore., , Pakistan, Pakistan
27.	040816	Fambria Suspension Famotidine... 10mg	Ambrosia Pharmaceuticals,, Plot No.18, St. No.9, National Industrial Zone, Rawat, Islamabad., , Pakistan, Pakistan
28.	041444	Famo Rains Suspension Famotidine ……10 mg	MAC AND RAINS PHARMACEUTICALS (PVT) LIMITED, Lahore., , Pakistan, Pakistan
29.	041472	Hifame Suspension Famotidine …… 10mg	Hicon Pharmaceuticals, 131 Industrial Estate Hayatabad, Peshawar., , Pakistan, Pakistan
30.	041619	Servipep Susp. Famotidine…….10mg	Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar., , Pakistan, Pakistan
31.	042764	Fastine Suspension Famotidine ……..10mg	Trigon Pharmaceutical (Pvt) Limited, 18 Km Raiwind Road, Lahore
32.	042966	Nocer 10 Suspension Famotidine……..10mg	Bryon Pharma (Pvt) Ltd,, 48 Hayatabad, Indus. Estate, Peshawar.
33.	043409	Sypep Suspension Famotidine……10 mg	Alsons Pharmaceuticals, 169-Hayatabad Industrial Estate, Peshawar.
34.	043731	Ulcare.Suspension.10mg. Famotidine……10mg	Z-JANS Pharmaceuticals,, 148-A, Industrial Estate, Hayyatabad, Peshawar, , Pakistan, Pakistan
35.	044794	Famofit Suspension Famotidine ……..…10mg	M/s Synchro Pharmaceuticals,, 77-Industrial Estate, Kot Lakhpat, Lahore., , Pakistan, Pakistan
36.	045470	Pharmotidin Suspension Famotidine. …….. 10 mg	Epharm Labs, , Karachi, , Pakistan, Pakistan
37.	046936	H2foz Suspension Famotidine ……..10mg	Fozan Pharmaceuticals (Pvt) Ltd, 36-A, industrial Estate,

			Hayatabad, Peshawar, , Pakistan, Pakistan
38.	047354	Zebid Suspension Famotidine……10mg	Atco Laboratories Limited, , B-18, SITE, Karachi., , Pakistan, Pakistan
39.	047829	Famonil Suspension 60ml Famotidine……..10 mg	Hisun Pharmaceuticals, , Plot.No.37 Road No, R-2, Industrial Estate Gadoon, Swabi., , Pakistan, Pakistan
40.	052452	Fam-PH Suspension. Famotidine……..10mg	Evergreen Pharmaceuticals,, Sundar Industrial Estate, Lahore., , Pakistan, Pakistan
41.	054223	Myolif Suspension Famotidine……..10mg	Life Pharmaceutical Company, , 24-III, Industrial Estate, Multan
42.	054287	Stomachcare Susp Each 5ml contains:- Famotidine 10mg	Jawa Pharmaceuticals (Pvt.) Ltd., , , ,
43.	054455	Famosin Suspnesion Famotidine 10mg	Irza Pharma (Pvt) Ltd, 10/2 Km Sheikhupura Road, P.O.Kot Abdul Malik, Sheikhupura..
44.	054613	Efdine Suspension Famotidine……..10mg	Meditech Pharmaceuticals,, 15-D Industrial Estate, Jamrud Road, Peshawar, , Pakistan, Pakistan
45.	054717	Afomit Susp Famotidine ……..10mg	Alliance Pharmaceuticals (Pvt) Ltd, 112-A, Industrial Estate, Hayatabad, Peshawar., , Pakistan, Pakistan
46.	055103	Famdin Suspension Famotidine……10mg	Pakistan Pharmaceuticals Products, Karachi, , Pakistan, Pakistan
47.	055282	Almadine Suspension 10mg/5ml Famotidine…10mg	Selomore Pharmaceuticals(Pvt)Ltd.,, 35 KM, Multan Raod, lahore, , Pakistan, Pakistan
48.	056653	Nogacid Suspension Famotidine…….10mg	LowittPharmaceutical(Pvt)Ltd , Plot.No.24 Industrial Estate, Peshawar., , Pakistan, Pakistan
49.	057740	Famtaza Dry Suspension Famotidine…..……..10mg	ZafaPharmaceuticals,, Karachi, , Pakistan, Pakistan
50.	058116	Atodine Suspension 10mg/5ml Famotidine ……..10 mg	Macquins International, Karachi, , Pakistan, Pakistan
51.	058152	Trump 10mg/5ml Suspension Famotidine……..10 mg	Adamjee Pharmaceuticals, Karachi, , Pakistan, Pakistan
52.	059498	Fedcid Suspension Each 5ml contains:- Famotidine 10mg	Fedro Pharmac (Pvt.) Ltd.,
53.	059540	Motidin Suspension Famotidine….10mg	Medley Pharmaceutical,, 41-A P.S.I.E Jhang Bahtar Road, Wah Cantt, , Pakistan, Pakistan

54.	059885	Gestrodine Suspension Each 5ml contains:- Famotidine…….10mg	Harmann Pharmaceutical Labs (Pvt) Ltd,, 16 -Km Multan Road, Lahore., , Pakistan, Pakistan
55.	059947	Gaster Suspension Famotidin ……. 10mg	Hamaz Pharmaceuticals (Pvt) Ltd,, 22 Km Lutafabad Road, Multan., , Pakistan, Pakistan
56.	060333	Famodex Suspension Famotidine …… 10mg	Ameer Pharma (Pvt) Ltd, , 23-KM, Sheikhupura Road,Lahore., , Pakistan, Pakistan
57.	061150	Flut Suspension Famotidine……..……10mg	Zephyr, Karachi, , Pakistan, Pakistan
58.	061758	Kohiton Suspension Famotidine……..10mg	KohsPharmaceuticals,, P8,SITE,Phyderabad, , Pakistan, Pakistan
59.	062698	NO-UL Suspension Famotidine ……10mg	Fynk Pharmaceuticals,, 19 K.M. G.T. Road, Kala Shah Kaku, Lahore., , Pakistan, Pakistan
60.	063004	Famoday Suspension Each 5ml contains:- Famotidine 10mg	Max Pharmaceuticals, , , ,
61.	063081	Pepcimed Suspension 10mg/5ml Famotidine…….10mg	MedicraftPharmaceuticals(Pvt)Ltd, 126-B, Industrial Estate, Jamrud Road, Peshawar., , Pakistan, Pakistan
62.	064293	S.Famers 10mg Syrup Famotidine……..10mg	SayyedPharmaceuticals(Pvt)L td.,, Plot No.67/2 Phase 3, Industrial Estate, Hattar, , Pakistan, Pakistan
63.	064891	Famoprime Suspension 10mg Famotidine ……10mg	Prime Labs (Pvt) Ltd, , 9.5 Km Sheikhupura Road, Lahore., , Pakistan, Pakistan
64.	065555	Therafame Suspension 10mg/5ml Famotidine…..10mg	Theramed Pharmaceutical, , 331-J-1 Johar Town Lahore, , Pakistan, Pakistan
65.	065677	Famid 10mg Suspension Famotidine……10mg	Wilshire Laboratories,, 124/A, Kotlakhpat, Indus. Area, Township Scheme, Lahore., , Pakistan, Pakistan
66.	065956	Famotop Suspension Famotidine…… 10mg	Xenon Pharmaceuticals (Pvt) Ltd, , 9.5 KM Sheikhupura Road, Lahore, , Pakistan, Pakistan
67.	066298	Maripep Each 5ml contains:- Famotidine 10mg	Miracle Pharmaceuticals (Pvt.) Ltd., Islamabad, , Pakistan, Pakistan
68.	067940	Gdicd Suspension Famotidine…10mg	Unison Chemical Works, Lahore, , Pakistan, Pakistan
69.	069070	Femcare Suspension Famotidine ……10mg	Care Pharmaceuticals, 8-KM Thokar, Raiwind Road, Lahore., , Pakistan, Pakistan
70.	069396	Famtac Suspension Famotidine…10mg	Rasco Pharma,, 5.5 KM Raiwind Road Ali Razabad, Lahore, , Pakistan, Pakistan

71.	070711	Acicon 10mg/5ml Dry Suspension Famotidine …….10 mg	Barret Hodgson,, Karachi, , Pakistan, Pakistan
72.	071168	Famotidine 10mg/5ml Suspension Famotidine …… 10mg	Lawrence Pharma (Pvt.) Ltd, , 10.5Km Sheikhupura Road, Lahore., , Pakistan, Pakistan
73.	075050	Dinex Suspension Each 5 ml contians:- Famotidine … 10 mg	Gulf Pharmaceuticals, Plot No.4, St.No.S-6, National Industrial Zone, Rawat, , Pakistan, Pakistan
74.	075259	Modin Suspension Famotidine: 10mg	Metro Pharmaceuticals, Plot No. 14 St. No. SS-2 National Industrial Zone (RCCI) Rawat Islamabad, Islamabad, Pakistan, Pakistan
75.	077070	Feptid Oral Suspension Famotidine: 10mg	Axis Pharmaceuticals , 3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad., Faisalabad, Pakistan, Pakistan
76.	077441	Famonyx 10 Suspension Famotidine: 10mg	Onyx Pharamaceuticals Industries, 30-A SIE Mansehra, Mansehra, Pakistan, Pakistan
77.	078725	Al-Famot Oral Liquid Suspension 60ml Famotidine: 10mg	Ali Industries, Plot No.239/C Sundar Industrial Estate Raiwind Road Lahore., Lahore, Pakistan, Pakistan

Proceedings of 296th Meeting:

The Board discussed the case at length that the above formulations are registered since long. As per available record and reviewing of information available at websites of RRAs, no data regarding their safety and efficacy is available in such strengths/dosage forms, so continuity of these formulations is not justifiable. Furthermore, scrutiny of data revealed that there also exists a number of formulations, which were never approved in the strengths currently registered in the country, while, others have strengths identical to that approved by reference regulatory authorities but have different dosage forms.

Board emphasized the significance of recognition of RRAs as adopted by it since long. RRAs includes robust regulatory authorities of world like US-FDA, EMA, Health Canada, TGA Australia etc. etc. The concept of reliance on decisions of reference regulatory authorities assure the safety, efficacy, and quality of medicines. This reliance enables to have evidence for robust and accurate decision-making, considering that the products registered and sold in the countries of reference regulatory authorities fulfil the harmonized standards of safety, efficacy and quality as adopted by WHO, ICH, etc. This reliance also enables the national regulatory authority for post marketing surveillance particularly related to safety and efficacy issues. Reference regulatory authorities have stronger reporting and information sharing system, which can be used by national regulatory authorities as a useful tool for surveillance, new available treatments and new indications or contraindications.

It was also discussed that certain formulations were previously approved by reference regulatory authorities but later on withdrawn due to following reasons:

- Commercial/ marketing issues.
- Safety concerns.

In this context, all members endorsed the above stated facts and shared their views on the subject matter, which have been consolidated as under:

- Policies/ practices adopted by different countries regarding such formulations were discussed and it was concluded that it is reasonable to continue with such formulations in those countries, which have a well-developed regulatory system for reporting of adverse events and addressing of safety issues. While, there also exists examples of countries where a number such

formulations have been withdrawn. However, in current health care system working in our country, safety cannot be established as ADRs reporting system is not well anchored.

- Once a product is discontinued in reference regulatory authorities due to safety reasons, the information regarding its label/ patient information leaflet (PIL), medical literature, clinical use, route of administration, dosage, storage conditions of finished products and type of container closure system/packaging material etc will not be available as a reference/ standard to be adopted by a local manufacturer, which is required as per conditions of registration.
- If a product has no evidence of availability/ approval in the Reference Regulatory Authorities or it was available in the past but now withdrawn due to marketing/ commercial etc. issues and not because of safety reasons.
- Therefore, there is a need to resolve the issue by taking administrative measures/ decision. Furthermore, all such cases need to be evaluated/ decided on case to case basis considering scientific grounds, therapeutic equivalencies and pharmacodynamic aspects provided that the strength remains same as available/ approved in reference regulatory authorities. In this regard, a working group may be created having members from Registration Board with relevant specialty and stake holders.

Decision: **Registration Board deliberated the case in the light of above stated facts / opinions and decided as under:**

i. **Since, all such formulations which are not approved by the Reference Regulatory Authorities; the safety and efficacy profile cannot be established in the absence of a well-established system for reporting of adverse events, so a reference shall be forwarded to DRAP's Authority with the request to review the decision taken in its 70th meeting held on 05-09-2019. In this regard, PE&R Division shall prepare a comprehensive document/agenda for consideration of Authority, keeping in view the practices adopted by RRA for all such formulations;**

ii. **For all those formulations which are registered/ applied in strengths, different from those approved by reference regulatory authorities, the registration holders/ applicants shall standardize their formulations (by submitting registration application with requisite fee, provided that the firm did not have same registration) in line with those approved by reference regulatory authorities. In this regard, recommendation shall be forwarded to DRAP's Authority to exempt all such cases/applications for standardization of formulation to be submitted on Form-5F/CTD format as notified vide SRO 713(I)/2018 dated 09-06-2018.**

iii. **Drug products withdrawn from RRA due to any commercial reason shall be considered for registration by Registration Board.**

iv. **Vitamin-mineral formulations will be considered as per vitamin policy approved by Policy Board and further adopted by Registration Board in its 295th meeting.**

Case No.21. De-Registration of Darcin Capsule of M/s Bloom Pharmaceuticals (Pvt) Ltd, Hattar

M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No. 30, Phase I & II Industrial Estate Hattar has applied for de-registration of their following registered product.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	077486	Darcin-250mg Capsules Each capsule contains:- Azithromycin dihydrate ≡ Azithromycin……250 mg (USP Specification)	The product was registered on 08-11-2013 but the renewal was delayed & product was not renewed with differential fee. Due to this the firm has applied new registration of the product which is approved in 295th meeting of Registration Board.	Not provided	08-11-2013

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
a. Justification.

Following documents have not been submitted by the firm:

a. List of alternate brands available in the country.
b. An Undertaking that:
    i. No case is pending at any forum/ court of law regarding above mentioned products.
    ii. Provided information/ documents are true/ correct.

Decision: **Registration Board acceded to the request of M/s Bloom Pharmaceuticals (Pvt) Ltd, Hattar for de-registration of "Darcin-250mg Capsule" (R#077486) due to non-submission of renewal application within due date. Furthermore, the firm shall submit undertaking in the light of SOP approved vide 283rd meeting of Registration Board.**

Case No.22. Cancellation of Registration of Registered Products of M/s Pakistan Pharmaceutical Products, (Pvt) Ltd., Karachi

M/s Pakistan Pharmaceutical Products, (Pvt) Ltd., D-122, Sindh Industrial Trading Estate, Karachi has applied for de-registration of their following registered products:

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status (provided by the firm)
	004017	Oxymycin Capsule 250mg Oxytetracycline	No market demand as very old molecule	Not provided	03-05-1978 Last renewed on 03-05-2008 for further period.
	012097	Erin Tablet Each tablet contains: Ethambutal….300mg Rifampicin….150mg INH……..…75mg	Out dated combination- No market demand	Not provided	26-12-1990 Last renewal submitted on 27-11-2010
	007393	Okasa Tablet Each tablet contains: Methyl Testosterone…5mg Yohimbine HCl……3.5mg Strychnine Glycerophosphate….0.3mg Callcium Glycerophosphate….7mg Vitamin E…….2.5 mg Caffeine……..15mg	Company does not have Hormone Section.	Not provided	27-05-1994 Last renewed on 27-05-2014 for further period.
	005918	Chlorpromazine Tablets 25mg	No market demand as very old molecule	Not provided	18-04-1982 Last renewal submitted on 10-04-2017
	005420	Tetracycline Capsule 250mg	No market demand as very old molecule	Not provided	29-07-1980 Last renewal submitted on 05-07-2010

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

b. Copy of Registration Letter & Last Renewal Status.
b. Justification.
c. An Undertaking that:
   i. No case is pending at any forum/ court of law regarding above mentioned products.
   ii. Provided information/ documents are true/ correct.

Following documents have not been submitted by the firm:

a. List of alternate brands available in the country.

Decision: Registration Board referred to Drug's availability committee for their evaluation and comments.

Case No.23. License Withdrawal of Registered Products of M/s Sanofi Aventis Pakistan Ltd., Karachi

M/s Sanofi Aventis Pakistan Ltd., Plot No.23, Sector No.22, Koramgi Industrial Area, Karachi has applied for withdrawal of registration license of their following registered products:

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status (provided by the firm)
1.	017264	Lactacyd Liquid Each 100ml contains: Lactoserum Spray Dried…0.930gm Lactic Acid…..1gm Ammonium and Triethanolaminealkylsulphates…..18gm	➢ The product is a daily feminine hygiene wash to maintain the physiological equilibrium of the mucosa. ➢ The decision is not related to safety, quality and efficacy of the product. ➢ The product is not in essential drug list of Pakistan, whereas similar products are freely available in the market.	Not provided	18-04-1995 (in the name of M/s Searle, Karachi) Transfer of registration to M/s Sanofi-Aventis, Karachi dated 02-10-2007 Last renewal submitted on 04-08-2016
2.	070435	Gastrolyte Fruit Sachet Each Sachet of 4.885gms contains: Sodium Chloride…0.47gm Potassium Chloride…0.3gm Sodium acid Citrate….0.53gm Dextrose Monohydrate…3.56gm Silicon Dioxide (Aerosil)….0.009gm	➢ The decision is not related to safety, quality and efficacy of the product. ➢ A Number of alternative are freely available in the market.	➢ Paedicare by M/s Woodwards ➢ Peditral by M/s The Searle Company ➢ Osmolar by M/s Atco Laboratories	22-04-2011 Last renewed submitted on 25-03-2016.
3.	070436	Gastrolyte Rice Sachet Each Sachet of 7.45gms contains: Rice Powder…….6gm Sodium Citrate….0.58gm Sodium Chloride…0.35gm Potassium Chloride…0.30gm			

		HPMC (Pharmacoat 606)……..…0.36gm			
4.	070437	Gastrolyte Orange Sachet Each Sachet of 5.177gms contains: Sodium Chloride…0.47gm Potassium Chloride…0.3gm Sodium acid Citrate….0.53gm Dextrose Monohydrate…3.56gm Silicon Dioxide (Aerosil)….0.009gm			

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
c. Justification.
d. An Undertaking that:
   i. No case is pending at any forum/ court of law regarding above mentioned products.
   ii. Provided information/ documents are true/ correct.

Following documents have not been submitted by the firm (for products at S.No.1):

a. List of alternate brands available in the country.

Decision: Registration Board referred to Drug's availability committee for their evaluation and comments.

Case No.24. Intimation for Discontinuation of Production of Marketed Products of M/s Getz Pharma (Pvt) Ltd., Karachi

M/s Getz Pharma (Pvt) Ltd., 29-30/27, Korangi Industrial Area, Karachi has intimated regarding discontinuation of production of their following marketed products under Rule 30 of Drugs (L,R&A) Rules, 1976 which states to intimate Registration Board about the circumstances which may lead to reduction in the production of drug and may result in its shortage.

S/N	Reg. No.	Brand Name and Composition	Justification
1.	061706	Cinita Tablet Each tablet contains:- Cinitapride (as acid tartarate) ..1mg	Demand of product is far lesser than the minimum batch quantity of the product, which can be manufactured on the equipment.
2.	075965	Cipesta XR 500mg Tablet Each extended release tablet contains: Ciprofloxacin: 500mg	

Decision: Registration Board referred to Drug's availability committee for their evaluation and comments..

Case No.25. Withdrawal of De- Registration Request for Products of M/s GSK Pakistan Limited, Karachi.

M/s GSK Pakistan Limited, Karachi has requested for withdrawal of their previously submitted request for de-registration of their following registered products.

S. No.	Reg.No.	Brand name and composition	Justification Submitted by the Firm	Date of Registration & Last Renewal Status Provided by the firm	Remarks
I	II	III	IV	V	VI
1.	009574	Capozide Tablet 50mg Each tablet contains: Captopril…….50mg Hydrochlorothiazide….25mg	Based on revised commercial decision the firm has decided to retain these products/ licenses. These products currently have valid licenses.	26-02-1987 17-09-2015	Case for de-registration was considered in M-286 and referred to DRAP's Committee for availability of drugs for its opinion.
2.	004035	Tagamet Tablet 200mg Each tablet contains: Cimetidine……200mg		03-05-1979 14-12-2018	
3.	006364	Tagamet Tablet 400mg Each tablet contains: Cimetidine……400mg		18-05-1982 08-08-2018	
4.	089270	Tagamet Injection Each 2ml contains: Cimetidine HCl….200mg		06-06-2018	Applied for de-registration on 29-01-2018

Decision: Registration Board referred the matter to Legal Affair Division for their comments on firm's request.

Case No.26. Request for change in Registration Status of Product from M/s Barrett Hodgson, Karachi to M/s Martin Dow Marker Limited, Quetta.

M/s Martin Dow Marker Limited, 7, Jail Road, Quetta has requested for change in registration status of Toradol Injection, Ketorolac Tromethamine 30mg/ml (R#015000) from M/s Barrett Hodgson, F/423, S.I.T.E., Karachi to their name. Detail is given as under:

1.	**Name, address of Applicant / Marketing Authorization Holder**	**Martin Dow Marker Limited**
	Name, address of Manufacturing site.	Martin Dow Marker Limited, 7, Jail Road, Quetta, Pakistan.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8813 (R&I) dated 23-04-2020
	Details of fee submitted	PKR 20,000/-: 26-11-2019
	The proposed proprietary name / brand name	**Toradol Injection 30mg/ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each 1ml ampoule contains: Ketorolac Tromethamine…..…30mg"
	Pharmaceutical form of applied drug	Parentral (Injection)
	Pharmacotherapeutic Group of (API)	Acetic Acid Derivative and related Substances ATC Code: M01AB15
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Health Canada approved Ketorolac Tromethamine Injection
	For generic drugs (me-too status)	K-Dol (Akson Pharmaceuticals) Reg. No. 060042
	Name and address of API manufacturer.	M/s. Satyadivis Pharmaceuticals Pvt. Ltd., Survey No. 10, Gaddapotaram Village, Khazipally Indl. Estate, Jinnaram Mandal, Sangareddy Dist.-502 319. Telangana State INDIA. Tel. +91-8458-277227
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated (40˚C ± 2˚C / 75% ± 5%RH) and real time (25˚C ± 2˚C / 60% ± 5%RH) conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence	The firm has submitted results (of all the quality tests (mentioned in USP) and comparison of Toradol lnjection 30mg/ml, Batch No. C0525 manufactured by Barret Hodgson Pakistan (Pvt.) Ltd. and Toradol lnjection 30mg/ml, Batch No. 1DF manufactured by Martin Dow Marker Ltd. Test results of this study found satisfactory, comparable and within specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method verification data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	M/s. Satyadivis Pharmaceuticals Pvt. Ltd., Survey No. 10, Gaddapotaram Village, Khazipally Indl. Estate, Jinnaram Mandal, Sangareddy Dist.-502 319. Telangana State INDIA. Tel. +91-8458-277227		
API Lot No.	0171018		
Description of Pack (Container closure system)	The solution of Toradol injection 30mg/ml is filled in the clear glass ampoules Type I (Primary Packaging Materials). Injections are blistered into the Polycoated paper and PVC of 1x5's Ampoules.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	1DF	2DF	3DF
Batch Size	5 Liters	5 Liters	5 Liters
Manufacturing Date	01-2019	01-2019	01-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP certificate (25885/TS/2019) issued by the by the Drug Control Administration, Government of Telangana, has been submitted which is valid upto 03-10-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

<table>
<tr><td>5.</td><td>Documents confirming import of API etc.</td><td>Ketorolac Tromethamine: Copy of commercial invoice attested by AD I&E DRAP, Quetta, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th><th>Date of approval by DRAP</th></tr>
<tr><td>0171018</td><td>KET/EXP/084/2018-19</td><td>1.5KG</td><td>07-12-2018</td></tr>
</table></td></tr>
<tr><td>6.</td><td>All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.</td><td>Yes</td></tr>
<tr><td>7.</td><td>Commitment to continue real time stability study till assigned shelf life of the product.</td><td>Yes</td></tr>
<tr><td>8.</td><td>Commitment to follow Drug Specification Rules, 1978.</td><td>Yes</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR</td></tr>
<tr><td colspan="3">The firm has submitted following information/ documents in the light of SOP approved in 283rd meeting of Registration Board:

Copies of initial letter of registration and renewal status (i.e. application received within due date)

<table>
<tr><th>Reg. No.</th><th>Name and Composition of Drug (s)</th><th>Registration Details</th></tr>
<tr><td>015000</td><td>Toradol IM 30mg/ml
Each ml contains:
Ketorolac Tromethamine as Ketorolac Trometamol</td><td>i. Transfer of Registration from M/s Martin Dow Pharmaceuticals, Karachi to M/s Barrett Hodgson Pakistan (Pvt) Ltd., Karachi dated 15-06-2011.
ii. Transfer from import to local manufacture dated 27-06-2011.
iii. Last Renewal dated: 14-04-2016.</td></tr>
</table>
<ol start="2">
Copy of last GMP inspection report dated 12-07-2019 (Good Level of Compliance).
Panel Inspection Report dated 13th-14th May, 2016 for renewal of DML as evidence of approval of “Sterile Liquid Injection (General) Section”.
NOC from M/s Barrett Hodgson, F/423, S.I.T.E., Karachi dated 17-04-2020.
</td></tr>
</table>

Decision: Registration Board deferred the case for following;

- **a. Review of application as per decision of Registration Board in 293rd meeting.**
- **b. Submission of stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Board in its 290th meeting under “Requirement of The Storage Conditions for The API Stability and FPP Stability”.**

Case No.27. Request for Change in Registration Status of Product from M/s Hilton Pharma (Pvt) Ltd., Karachi to M/s Healthtek (Pvt) Ltd., Karachi Through Contract Manufacturing at M/s Stallion Pharmaceuticals (Pvt) Ltd., Lahore.

M/s Healthtek (Pvt) Ltd., Plot No.14, Sector 19, Korangi Industrial Area, Karachi has requested for change in registration status of Mopen (Meropenem) Injection 500mg (R#036429) & 1gm (R#036427) from M/s Hilton Pharma (Pvt) Ltd., Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi to their name through contract manufacturing at M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore. Detail is given as under:

i. MOPEN Injection 500mg

1.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sundar Industrial Estate, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) **☒ Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8187 (R&I) dated 20-04-2020
	Details of fee submitted	PKR 50,000/-: 20-04-2020
	The proposed proprietary name / brand name	MOPEN Injection 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as Meropenem Trihydrate)……500mg
	Pharmaceutical form of applied drug	Dry Powder For Injection
	Pharmacotherapeutic Group of (API)	Broad Spectrum Carbapenem Beta Lactam Antibiotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved in FDA (MERREM 500mg Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 500mg Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 500mg Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated (40˚C ± 2˚C / 75% ± 5%RH) and real time (25˚C ± 2˚C / 60% ± 5%RH) conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has submitted results (of all the quality tests (mentioned in USP) and comparison of Merostin Injection, Batch No. U0003 manufactured by M/s Stallion and Meronem Injection, Batch No. 4B19J211 of M/s Pfizer. Test results of this study found satisfactory, comparable and within specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method verification data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA	
Manufacturer of API	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India
API Lot No.	1705203623(Batch #)
Description of Pack (Container closure system)	USP type III colorless glass vials with flip-off aluminium seal.
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH

	Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 24 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T6001	T6002	T6003
Batch Size	15870 vials	15870 vials	7870 vials
Manufacturing Date	July-2016	July -2016	Oct-2016

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted copy of commercial Invoice having following information Invoice No: U05/17-18/776 dt:10-10-17 ADC Attested Invoice dated: 19-10-2017 Quantity: 20 Kg Batch No. 1705205096-10kg Batch No. 1705205135-10kg
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATORS

The firm has submitted following information/ documents in the light of SOP approved in 283rd meeting of Registration Board:

1. Copies of initial letter of registration and renewal status.
2. Copy of last GMP inspection report of M/s Stallion dated 16-09-2019 (**Satisfactory** Level of Compliance).
1. Approval of "Dry Powder Injection Vial (Carbapenem) Section" of M/s Stallion issued by Licensing Division vide letter dated 08-02-2016.
3. NOC from Hilton Pharma (Pvt) Ltd., Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi dated 10-02-2020.
4. Copy of Contract Agreement.

M/s Stallion has further informed that:

They will contract with M/s Renacon Pharma Ferozpur Road, Lahore, for the analysis of Na Content in Meropenem injection. In future, they will proceed with them or may arrange AAS for their laboratory.

ii. MOPEN Injection 1g

1.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Healthtek (Pvt.) Limited. Plot No. 14, Sector 19, Korangi Industrial Area Karachi
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd., 581-Sundar Industrial Estate, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) **☒ Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8188 (R&I) dated 20-04-2020
	Details of fee submitted	PKR 50,000/-: 20-04-2020
	The proposed proprietary name / brand name	MOPEN Injection 1g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as Meropenem Trihydrate)……1g
	Pharmaceutical form of applied drug	Dry Powder For Injection
	Pharmacotherapeutic Group of (API)	Broad Spectrum Carbapenem Beta Lactam Antibiotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved in FDA (MERREM 1g Injection M/s. AstraZeneca USA) Approved in EMA (MERONEM 1g Injection M/s. Pfizer UK)
	For generic drugs (me-too status)	PENRO IV 1g Injection M/s, Bosch Pharma
	Name and address of API manufacturer.	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated (40˚C ± 2˚C / 75% ± 5%RH) and real time (25˚C ± 2˚C / 60% ± 5%RH) conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has submitted results (of all the quality tests (mentioned in USP) and comparison of Merostin Injection, Batch No. U0003 manufactured by M/s Stallion and Meronem Injection, Batch No. 4A19J15 of M/s Pfizer. Test results of this study found satisfactory, comparable and within specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method verification data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA			
Manufacturer of API	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India		
API Lot No.	1705203623(Batch #)		
Description of Pack (Container closure system)	USP type III colorless glass vials with flip-off aluminium seal.		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 24 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	U6001	U6002	U7001
Batch Size	23800 vials	19680 vials	15360 vials
Manufacturing Date	July-2016	Oct-2016	Jan-2017

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**

1.	COA of API.	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	M/s AUROBINDO Pharma, India. Unit-V. Plot No. 68-70, 79-91, 95,96,260,261, I.D.A, Pashamylaram, Sangareddy Dist. Telangana State, India
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted copy of commercial Invoice having following information Invoice No: U05/17-18/776 dt:10-10-17 ADC Attested Invoice dated: 19-10-2017 Quantity: 20 Kg Batch No. 1705205096-10kg Batch No. 1705205135-10kg
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATORS

The firm has submitted following information/ documents in the light of SOP approved in 283rd meeting of Registration Board:

1. Copies of initial letter of registration and renewal status.
2. Copy of last GMP inspection report of M/s Stallion dated 16-09-2019 (**Satisfactory** Level of Compliance).
3. Approval of "Dry Powder Injection Vial (Carbapenem) Section" of M/s Stallion issued by Licensing Division vide letter dated 08-02-2016.
4. NOC from Hilton Pharma (Pvt) Ltd., Plot No.13 & 14, Sector 15, Korangi Industrial Area, Karachi dated 10-02-2020.
5. Copy of Contract Agreement.

M/s Stallion has further informed that:
They will contract with M/s Renacon Pharma Ferozpur Road, Lahore, for the analysis of Na Content in Meropenem injection. In future, they will proceed with them or may arrange AAS for their laboratory.

Remarks of RRR Section regarding Renewal Status:

Renewal application of year 2019 received on 31-12-2019 while due date was 30-12-2019 under Rule 27 of Drugs (L, R &A) Rules,1976. Therefore, renewal was received late but within 60days. Firm has submitted late fee of Rs. 60000 dated 28-07-2020 vided challan No. 2032362 (Mopen 500mg) & 2032363 (Mopen 1gm).

Proceedings of M-296:

The Board was apprised that in addition to above mentioned remarks following observations have been recorded while evaluation:

i. Provided stability studies of API have not been performed as per conditions of Zone-IV-A.
ii. The firm has submitted formulation development studies, batch analysis reports and stability studies (regardless of stating API Lot No.) which were performed in 2016 while developing their registered

product (Merostin Injection). However, as evidence for procurement of API, the firm has submitted AD attested invoice dated 10-10-2017. Therefore, complete trail couldn't be established.

iii. The firm has informed that analysis at that time was performed on manual HPLC that is why audit trail reports are not available for analysis performed before Januray, 2016.

iv. Analytical method verification studies of API and FPP (at that time) were not performed in line with the requirements (explanatory notes) set in 293rd meeting of Registration Board.

v. Compatibility studies of drug product with reconstitution diluent(s) have not been submitted.

Decision: Registration Board deferred the case for following;

a. Review of application as per decision of Registration Board in 293rd meeting.

b. Submission of stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Board in its 290th meeting under "Requirement of The Storage Conditions for The API Stability and FPP Stability".

c. submission of requisite information/ documents (as detailed above under proceedings of M-296)

Case No.28. Validity of Products Registration of M/s Alen Pharmaceuticals (Pvt) Ltd., Risalpur

Mr Zia Ullah, AD/FID-III, DRAP Peshawar, has informed (vide letter dated 03-02-2020) that during routine GMP inspection of M/s Alen Pharmaceuticals (Pvt) Ltd. 138, Nowshera Industrial Estate, Risalpur on 23-12-2019, it has been observed that apparently some of the registered products of the firm do not comply the Drugs (L, R & A) Rules, 1976, because the firm failed to provide registration renewal applications submitted within stipulated period for these products.

It has, therefore, been requested that validity of registration of those products for which the initial validity period has elapsed, may be evaluated as per law.

Detail of products as tabulated from registration letter copies provided by the firm at the time of inspection along-with remarks of RRR section regarding renewal status has been placed as under:

S.#	Name of Products	Reg.#	Letter No. & Date of Registration	Remarks of RRR Section
1.	Alendol Tablets 200mg	041038	F.13-3/2005-Reg-II-(M-191), Dated 08/08/2005	Renewal application of product is received within due date under Rule 27 L,R & A Rules, 1976.
2.	Alenprol Tablets 40mg	076891	F.13-1/2013-Reg-IV-(M-237), Dated 20/05/2013	Renewal application of product is received late but within 60 days. In this regard, additional fee & regularization by the RB is required.
3.	Dicgesic-K Tablets 75mg	076892	F.13-1/2013-Reg-IV-(M-237), Dated 20/05/2013	Renewal application of product is received late but within 60 days. In this regard, additional fee & regularization by the RB is required.
4.	Alencip Tablets 250mg	076893	F.13-1/2013-Reg-IV-(M-237), Dated 20/05/2013	Renewal application of product is received late but within 60 days. In this regard, additional fee

				& regularization by the RB is required.
5.	Alencip Tablets 500mg	076894	F.13-1/2013-Reg-IV-(M-237), Dated 20/05/2013	Renewal application of product is received late but within 60 days. In this regard, additional fee & regularization by the RB is required.
6.	Alenoliv Tablets 500mg	076895	F.13-1/2013-Reg-IV-(M-237), Dated 20/05/2013	Renewal application of product is received late but within 60 days. In this regard, additional fee & regularization by the RB is required.
7.	S. Alen Capsule 40mg	078513	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Received after expiry (01 year late) i.e., invalid under Rule 27 L,R & A Rules, 1976.
8.	Alenolive Tablets 250mg	078509	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Received after expiry (01 year late) i.e., invalid under Rule 27 L,R & A Rules, 1976.
9.	A-Mycin Tablets 250mg	078510	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Received after expiry (01 year late) i.e., invalid under Rule 27 L,R & A Rules, 1976.
10.	A-Mycin Tablets 500mg	078511	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Received after expiry (01 year late) i.e., invalid under Rule 27 L,R & A Rules, 1976.
11.	Locsim Tablets 400mg	078512	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Received after expiry (01 year late) i.e., invalid under Rule 27 L,R & A Rules, 1976.
12.	Fanlo Tablet 40mg	032446	F.3-1/2004-Reg-II-(M-182), Dated 05/08/2004	Found in the available record, with similar Reg. No. (Duplicate with Polyfine Chempharma but different product name)
13.	Zinclo Tablet 10mg	032447	F.3-1/2004-Reg-II-(M-182), Dated 05/08/2004	Found in the available record, with similar Reg. No. (Duplicate with Polyfine Chempharma but different product name)
14.	Dictasium Tablet 50mg	032448	F.3-1/2004-Reg-II-(M-182), Dated 05/08/2004	Found in the available record, with similar Reg. No. (Duplicate with Polyfine Chempharma

				but different product name)
15.	Alenmol Tablets	077487	F.11-3/2013-Reg-IV (M-218), Dated 08/11/2013	Not found in available record of RRR Section.
16.	I-Mec Tablets 6mg	078421	F.13-3/2013-Reg-IV-(M-239), Dated 13/12/2013	Not found in available record of RRR Section.
17.	Asterdic Tablets 75mg	043358	F.13-1/2006-Reg-II-(M-195-A), Dated 12/9/2006	Not found in available record of RRR Section.
18.	Alenzole Capsule 30mg	034733	F.3-2/2004-Reg-II-(M-183), Dated 01/12/2004	Not found in available record of RRR Section.
19.	Dolint Tablet 15mg	034399	F.3-4/2004-Reg-II-(M-186), Dated 19/11/2004	Not found in available record of RRR Section.
20.	Alenprox Dispersible Tablets 20mg	034489	F.3-4/2004-Reg-II-(M-186), Dated 19/11/2004	Not found in available record of RRR Section.
21.	Hypotec Tablet 10mg	027758	F.3-2/2002-Reg-II-(M-170), Dated 06/06/2002	Not found in available record of RRR Section.
22.	Panex Tablets 20mg	027759	F.3-2/2002-Reg-II-(M-170), Dated 06/06/2002	Not found in available record of RRR Section.
23.	Vermit Tablets 500mg	025808	F.3-4/2000-Reg-II-(M-153), Dated 18/05/2000	Not found in available record of RRR Section.
24.	Norex Tablets	025809	F.3-4/2000-Reg-II-(M-153), Dated 18/05/2000	Not found in available record of RRR Section.
25.	Durafenic Tablets 50mg	023702	F.3-7/2001-Reg-II-(M-164), Dated 24/08/2001	Not found in available record of RRR Section.
26.	Ibufer Tablets 400mg	026395	F.6-26/2000-Reg-II(AB), Dated 04/01/2001	Not found in available record of RRR Section.
27.	DIA-STILL Tablets 500mg	003174	F.3-5/97-Reg-II (M-127), Dated 23/09/1997	Not found in available record of RRR Section.
28.	Vitamax H Capsule	001704	F.3-5/97-Reg-II (M-127), Dated 23/09/1997	Not found in available record of RRR Section.
29.	Vitamax Forte C Capsules	002789	F.3-5/97-Reg-II (M-127), Dated 23/09/1997	Not found in available record of RRR Section.
30.	Vitamax F Tablets	038435	F.3-5/2004-Reg-II (M-186), Dated 26/05/2005	Not found in available record of RRR Section.
31.	Alendin Tablet	037496	F.3-7/2004-Reg-II (M-188-A), Dated 02/03/2005	Not found in available record of RRR Section.
32.	Alenpra Capsule	037497	F.3-7/2004-Reg-II (M-188-A), Dated 02/03/2005	Not found in available record of RRR Section.
33.	Al-One 1gm Injection	050416	F.3-1/2008-Reg-II-South (M-212), Dated 08/08/2008	Not found in available record of RRR Section.
34.	H-Caver Tablets 0.5mg	078508	F.13-2/2014-Reg-IV (M-242), Dated 25/04/2014	Not found in available record of RRR Section.

Decision: **Registration Board referred the case to RRR section for further processing at their end in the light of SOPs.**

Additional Agenda Minutes

Case No.01. Request for Change in Registration Status of Product from M/s Swat Pharmaceuticals to M/s Wahabsons Pharma (Pvt) Ltd. Swat Through Contract Manufacturing at M/s EG Pharmaceuticals, Islamabad.

M/s Wahabsons Pharma (Pvt) Ltd. Swat has requested for change in registration status of Soxime Capsule (Cefixime as Trihydrate 400mg) (R#060128) from M/s Swat Pharmaceuticals, Swat (existing contract manufacturer: M/s Biorex Pharmaceuticals, Islamabad) to their name through contract manufacturing at M/s EG Pharmaceuticals, Islamabad. Detail is given as under:

1.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Wahab sons pharma Pvt Ltd 4km Buner Road Barikot Swat
	Name, address of Manufacturing site.	EG Pharmaceuticals 13A Industrial Triangle, Kahuta road Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ✓☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ✓☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	✓☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.2942 : 27-02-2020
	Details of fee submitted	PKR 50,000/-: 25-02-2020
	The proposed proprietary name / brand name	**Soxime Capsules 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	"Each Capsule Contains: Cefixime (as Trihydrate)…….400mg
	Pharmaceutical form of applied drug	Capsules
	Pharmacotherapeutic Group of (API)	Third Generation Cephalosporin
	Reference to Finished product specifications	JP specification
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by FDA
	For generic drugs (me-too status)	Fixval Capsule (R#067071) of M/s GSK, Karachi
	Name and address of API manufacturer.	SAAKH PHARMA (Pvt)Ltd C-7/1,NWIZ,Port Qasim Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS –PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has also submitted results of comparative dissolution profile of their product with Fixval Capsule of M/s GSK. Firm has performed CDP in 0.1 N HCl, buffer pH 4.5 and phosphate buffer pH 6.8. Firm also calculated factor f2 which was above 50. The firm has submitted results and comparison of Fixval Capsule, manufactured by M/s GSK and Ficx Capsule of M/s EG. Test results of this study found satisfactory, comparable and within specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

STABILITY STUDY DATA

Manufacturer of API	SAAKH PHARMA (Pvt)Ltd C-7/1,NWIZ,Port Qasim Karachi		
API Lot No.	18CF10131,18CF10111,18CF10039		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No	961	990	933
Batch Size	3500packs	4370packs	4000packs
Manufacturing Date	03/2019	04/2019	02/2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP certificate 039/2019-DRAP (K) issued by the DRAP has been submitted. Which is valid up to 03-01-2020
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**N/A** As API Purchased from Saakh Pharma (Pvt)Ltd C-7/1,NWIZ, Port Qasim Karachi
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted following information/ documents in the light of SOP approved in 283rd meeting of Registration Board:

1. Copies of initial letter of registration and renewal status/ extension in permission of contract manufacturing valid upto 30.06.2020.
2. Copy of last Panel inspection report for renewal of DML of M/s EG dated 13-02-2019 as evidence of approval of "Cephalosporin Capsule Section" and GMP compliance.
3. NOC from M/s Swat Pharmaceuticals, Swat dated 25-02-2020.

The firm was asked to submit compatibility studies of the Drug Substance(s) with excipients shall be as the qualitative composition of the applied formulation was not similar to reference product. In response the firm has submitted revised composition i.e., qualitatively in line with that of reference product.

Decision:

i. **Cancellation of registration of Soxime Capsule (R#060128) from the name of M/s Swat Pharmaceuticals, Saidu Sharif, Amankot, Swat.**
ii. **Approved registration of Soxime Capsule in the name of M/s Wahabsons Pharma (Pvt) Ltd., 4KM, Buner Road, Barikot Swat through contract manufacturing at M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad.**
iii. **Reference will be sent to Costing & Pricing Division for confirmation of maximum retail price (MRP).**

Case No.1 Registration of Drug M/s. Allmed Pvt. Ltd; Lahore

Registration Board in its 229th meetings as mentioned below decided registration application of M/s. Evergreen, Lahore: -

S.No.	Name of Drug(s)	Demanded MRP	Decision of RB	Meeting reference
1.	Benajel Tablet Each tablet contains:- Sevelamer hydrochloride ….800mg (Phosphate binding)	As per SRO	Deferred for expert opinion	229th meeting

Later on, title of the firm has been changed to M/s. Allmed Pvt. Ltd, Lahore and they have submitted following documents.

They have submitted following documents and requested to grant them registration of above product:-

i. Duplicate dossier.
ii. Copy of Form-5.
iii. Firm has submitted photocopy of fee of Rs. 8000/- submitted by M/s. Evergreen Pharma and fresh submission of Rs.12000/- by M/s. Allmed Pvt.
iv. Change of company name letter from M/s. Evergreen to M/s. Allmed dated 26-03-2011.

Decision: Registration board deferred the case for submission of differential fee of Rs.8000/-.

Case No.2 Deferred cases of M/s Aptcure, Lahore.

Registration Board in its 229th meeting deferred the following products of M/s Aptcure, Lahore as follows:-

S. No.	Name of Drug(s)	Fee, Form and demanded Pack size	Decision of 229th meeting of the Board	Remarks
1.	Flomax Tablets Each film coated tablet contains:- Moxifloxacin B.P (as hydrochloride)……400mg (Quinolones(anti-biotics)	1x5's As per SRO	Deferred for GMP & product specific inspection	MHRA Approved The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section

The firm has provided copy of inspection report 24-11-2017 and requested to grant them registration of above products. Firm has submitted fee of Rs. 20,000/- dated 02-03-2020.

Decision: - Registration Board approved registration of above product in the name of M/s. Aptcure, Lahore.

Case No.3 Registration of Drugs M/s Harmann Pharmaceuticals Laboratories Pvt. Ltd. Lahore

Registration Board in its different meeting decided the following applications of M/s Harmann Pharmaceuticals Laboratories Pvt. Ltd. 16-Km Multan Road, Lahore. The details are given as under:-

S. No.	Name of Drug(s)	demanded Pack size	Decision of the Board	Remarks
1.	Amicin Injection Each 2ml contains: Amikacin as Sulphate .250mg Aminoglycoside.	Per Ampoule Rs.75/-	Deferred till decision on show cause. M-241	Product in reference regulatory authorities approved in strength of 250mg/ml but instant formulation is in strength of 250mg/2ml
2.	Amicin Injection Each 2ml contains: Amikacin as Sulphate ..500mg Aminoglycoside.	Per Ampoule Rs.150/-	Deferred till decision on show cause. M-241	MHRA approved Product is available in USP
3.	Methoriz Plus Tablet Each tablet contains: Artemether……..40mg Lumefantrine…….….240mg Antimalarial	8's / Rs.264/-	Deferred till decision on show cause. M-241	WHO Approved formulation Product is available in IP
4.	Moxiflox Tablet Each film coated tablet contains: Moxifloxacin as HCl…….400mg Quinolone.	5's / Rs.475/-	Deferred till decision on show cause. M-241	USFDA approved Product is available in USP
5.	Mecowel Tablets 500mcg Each tablet contains:- Mecobalamine……500mcg	10's As Per SRO	Deferred for GMP & product specific inspection M-229	Sugar coated tablet is approved in PMDA
6.	Actedril Syrup Each 5ml contains:- Triprolidine Hydrochloride…...1.25mg Pseudoephedrine Hydrochloride.....30mg Dextromethrophan Hydrobromide.....10mg	60ml As per SRO	Approved M-226	MHRA Approved

QA&LT Division vide letters No. F.8-4/2019-QA (M-261-CLB) dated 15th May, 2018 No. F.8-4/2019-QA (M-272-CLB) dated 6th December 2019 communicated that CLB in its 261st and 272nd meeting resumed the production activities of Tablet section (General) Capsule Section (General) Oral Liquid Syrup Section, Ointment/Cream Section and sterile Section II (Steroidal Injection Section) and in 272nd meeting resumed production activities of Sterile Section I (General) and Sterile Section II (Hormonal Injection)

Firm has submitted photocopies of fee challans of Rs. 8000/- and 12000/- for each product.

Decision: Registration Board decided as under;

i. **Approved the registration of products at Sr. No. 2-4 & 6. Fee shall beverifi ed as per procedure adopted by Registration Boardin .285th meeting**

ii. **Deferred the products at Sr. No. 1 & 5 for evidence of approval status of applied formulation in the reference regulatory authorities.**

Case No.4 Registration of Drug(s) M/s. Panacea Pharmaceuticals, Islamabad.

Registration Board in its various meetings has decided the following products of M/s. Panacea Phamraceuticals, Islamabad. The firm has requested that they have not yet received registration letter of the products. Details are given as under:-

S.No.	Name of Drug(s)	Demanded pack size	Demanded MRP	Decision of Registration Board.	Remarks
.1	Candecil 8mg Tablet Each tablet contains:- Candesartan Cilexetil …….…. 8mg (Panacea's Specification)	As per SRO.	As Per SRO	236th Meeting/ Approved	USFDA Approved
.2	Vaclovir 500mg Tablet Each film coated tablet contains:- Valaciclovir Hydrochloride eq. to Valaciclovir …… 500mg	As per SRO.	As Per SRO	236th Meeting/Approved	MHRA Approved
.3	Hyrose Eye Drops Each ml of ophthalmic solution contains:- Hypromellose …….. 3mg (USP Specifications)	5ml	As per SRO.	235th Meeting/Approved	MHRA Approved
.4	Tobrin-D Eye Drops Each ml of ophthalmic solutions contains:- Tobramycin …… 3mg Dexamethasone …….. 1mg (USP Specifications)	5ml	As per SRO.	235th Meeting/Approved	USFDA Approved
.5	Melas-P Cream Each gm contains:- Hydroquinone ……. 40mg Tretinoin ……. 0.5mg Fluocinolone Acetonide ……. 0.1mg (Paracea's Specifications)	15gm 30gm	As per SRO.	235th Meeting/Approved	USFDA Approved

They have submitted following documents and requested to grant them registration of above product:-

i. Duplicate dossier along with Form-5
ii. Photocopies of fee of Rs. 8000/- and 12,000/- for each.
iii. Section approval.

Decision: - Registration Board approved registration of above products in the name of M/s. Panacea Pharmaceuticals, Islamabad. Fee shall beverifi ed as per procedure adoptedby Registration Boardin .285th meeting

Case No.5 Registration of Drug(s), M/s. Sapeint Pharma, Lahore.

Registration Board in its 242nd and 295th meeting deferred the following products of M/s. Sapient Pharma, 123/S Kot Lakhpat Quaid Azam Industrial Area Lahore for GMP inspection panel comprising of Director DTL Lahore, DDG (E & M) & Area FID.

S/N	Product Name	Demanded MRP/Pack Size	Decision of Registration Board	Remarks
1.	Corflox Tablets Each film coated tablet contains:- Gemifloxacin Mesylate ……..320mg (antibacterial)	1. Form 5 2. Fast Track 3. 1050/7's 4. 05-07-13 (Rs. 60000/-)	Deferred for GMP by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID. M-242	The firm has submitted copy of panel inspection report dated 19-09-2019 & 18-11-2019 and GMP Certificate issued on 20-04-2020. USFDA Approved
2.	Cormide Tablets Each film coated tablet contains:- Leflunomide (B.P) …20mg (Antimetabolite: DMARD (Disease modifying antirheumatic drug)	1. Form 5 2. Fast Track 3. 1100/3×10's 4. 05-07-13 (Rs. 60000/-)	Deferred for GMP by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID. M-242	The firm has submitted copy of panel inspection report dated 19-09-2019 & 18-11-2019 and GMP Certificate issued on 20-04-2020. MHRA Approved
3.	Corfer-F Syrup Each 5ml contains:- Iron polymaltose complex equivalent to elemental iron (M.S) …….50mg Folic acid (B.P)…0.43mg (antianeamic)	1. Form 5 2. Fast Track 3. 120/120ml 4. 11-07-13 (Rs. 60000/-)	Deferred for GMP by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID. M-242	The firm has submitted copy of panel inspection report dated 19-09-2019 & 18-11-2019 and GMP Certificate issued on 20-04-2020. Iron preparations are not considered as drug by various reference regulatory authorities
4.	Oscaar Tablets Each tablet contains:- Losartan Potassium……50mg (Anti-hypertensive)	As per SRO /2x10's	**Deferred the products at Sr. No. 1-3, 6 & 7 for submission of fee as** Film coated tablet is approved in MHRA M-295	Firm has submitted fee of RS. 5000/- for correction from Uncoated to Film coated
5.	Atorvastat Tablet Each tablet contains:- Atorvastatin……10mg	As per SRO /1x10's	**Deferred the products at Sr. No. 1-3, 6 & 7 for**	Firm has submitted fee of RS. 5000/- for correction from

	(Anti-Atheromas)		**submission of fee** as Film coated tablet is approved in MHRA M-295	Uncoated to Film coated
6.	Atorvastat -20 Each tablet contains:- Atorvastatin……20mg (Lipid-Regulating Drugs)	As per SRO /1x10's	**Deferred the products at Sr. No. 1-3, 6 & 7 for submission of fee** as Film coated tablet is approved in MHRA M-295	Firm has submitted fee of RS. 5000/- for correction from Uncoated to Film coated
7.	Atlopin Tablets Each tablet contains:- Atorvastatin Calcium…….10mg Amlodipine besylate……..5mg (Calcium Antagonists)	Rs.200.00/10 Tablets	**Deferred the products at Sr. No. 1-3, 6 & 7 for submission of fee** as Film coated tablet is approved in USFDA M-295	Firm has submitted fee of RS. 5000/- for correction from Uncoated to Film coated
8.	Sapmin Tablets 500mcg Chewable Each tablet contains:- Mecobalamin……...500mcg (Co-enzyme Type vitamin B12)	Rs140.00/20 Tablets	**Deferred the products at Sr. No. 1-3, 6 & 7 for submission of fee** as Sugar coated tablet is approved in PMDA M-295	Firm has submitted fee of RS. 5000/- for correction from Chewable to Sugar coated

Decision: Registration Board decided as under;

i. **Approved the registration of products at Sr. No. 1-2, 4-8. Fee of products at Sr. No. 1-2 shall beverifi ed as per procedure adopted by Registration Boardin 285th .meeting**

ii. **Deferred the products at Sr. No. 3 for confirmation of me-too status.**

Case No.6 Registration of Drug(s), M/s. Don Valley Pharmaceuticals, Lahore.

Registration Board in its 212th meeting decided following registration application of M/s. Don Valley Pharmaceuticals (Pvt.) Ltd; Lahore. The details are given as under:-

S.No.	Name of Drug(s)	Demanded pack size	Demanded MRP	Decision of Registration Board.	Remarks
1.	Docodin Caplets. Each Tablet contains:- Paracetamol ……. 500mg Codeine Phosphate ... 15mg	10x10's	Rs.230.00	Deferred for policy/section.	MHRA Approved dosage form is Tablet **Firm has corrected their dosage form from Caplet to Tablet.**

Firm has submitted following documents:-

i. Duplicate registration application with revised Form-5

ii. Submission of fresh fee of Rs.20,000/-.

iii. Section approval of Tablet (Narcotics / Psychotropic).

Decision: - Registration Board approved registration of above product in the name of M/s. Don Valley Pharmaceuticals, Lahore with following formulation;

Docodin Tablet.
Each Tablet contains: -
Paracetamol ……. 500mg
Codeine Phosphate ... 15mg

Case No.7 M/s. Vision Pharmaceuticals Islamabad.

M/s Vision Pharma Islamabad had been granted three additional sections, enlisted below, in its 247th CLB meeting:

i.Liquid Ampoule (General)

ii. Liquid vial (General)

iii.Dry Powder Injection (Steroids)

The firm had submitted various applications against above cited sections. Registration Board in its 260th meeting had considered 10 molecules Liquid Ampoule (General) section.

In 264th DRB meeting the firm submitted to surrender three products due to marketing reasons, which were approved in 260th Registration Board meeting but the registration letter is awaited, and requested to consider three products tabulated hereafter.

Sr.#	Products considered in 260th RB meeting	Alternate products requested by Firm for replacement
1	Tramax 50 mg injection Each ampoule (1ml) contains : Tramadol Hydrochloride ……. 50 mg	Tramax 100 mg injection Each 2ml ampoule contain: Tramadol Hydrochloride…100 mg Opioid analgesics Manufacturer's Specifications
2	Zytec 25 mg Injection Each ampoule (1 ml) contains: Ranitidine Hydrochloride equivalent to Ranitidine……25 mg (USP Specifications)	Zytec 50 mg Injection Each 2ml ampoule contains: Ranitidine hydrochloride eq. to Ranitidine….. 50mg Histamine H2 Receptor Antagonist (U.S.P. Specifications)
3	Pyritec 150mg Injection Each ampoule (1 ml) contains: Paracetamol USP …. 150 mg (Manufacturere's Specifications)	Pyritec 300 mg Injection Each 2ml ampoule contain: Paracetamol USP…. 300 mg Analgesic & Antipyretic (Manufacturer's Specifications)

Registration Board did not accede to firm's request for replacement of already approved products with other applications. Now the firm has submitted that we do not intend to seek approval of any new molecule rather we have requested for additional strengths of our already approved molecules as enlisted below:

I. Tramax 50 mg injection
Each ampoule (1 ml) contains:
Tramadol Hydrochloride ……. 50 mg

II. Zytec 25 mg Injection
Each ampoule (1 ml) contains:
Ranitidine Hydrochloride equivalent to Ranitidine……25 mg
(USP Specifications)

Details of additional strengths of above formulations, requested by firm are as follows:

Sr.#	**Name and address of manufacturer / Applicant**	**Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification**	**Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size**	**Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the Evaluator**
	M/s Vision Pharma Plot 22-23 Industrial triangle, Kahuta road, Islamabad	Tramax 100 mg injection Each 2ml ampoule contain: Tramadol Hydrochloride … 100 mg Opioid analgesics	Form 5 17-10-2016 Dy No. 1670 Rs 20,000 17-10-2016 1*5's 1*10's As per SRO	MHRA-UK approved Symol Injection of M/s Indus Pharma Last inspection report 9-2-2016 Confirms GMP.
	M/s Vision Pharma Plot 22-23 Industrial triangle, Kahuta road, Islamabad	Zytec 50 mg Injection Each 2ml ampoule contains: Ranitidine hydrochloride eq. to ranitidine ….. 50 mg Histamine H2 Receptor Antagonist (U.S.P. Specifications)	Form 5 17-10-2016 Dy No. 1669 Rs 20,000 17-10-2016 1*5's 1*10's As per SRO	MHRA-UK approved Anine Injection of M/s Nexus Pharma Last inspection report 9-2-2016 Confirms compliance to GMP.

Registration Board in its 270th deferred for clarification regarding confirmation of date of submission of registration applications.

Now firm has submitted a letter regarding withdrawal of replacement letter and requested to issue registration letter of the product Tramax 50mg/ml Injection.

Registration Board in its 295th deferred for further deliberation with complete case.

Firm has now submitted a letter regarding withdrawal of previous undertakings regarding replacement of products considered in 260th meeting and requested to issue registration letter of the approved products Tramax 50mg/ml Injection and Zytec 25mg Injection.

Decision: - Registration Board acceded to request of the firm and decided to process the case as per decision of 260th meeting.

Case No.8 Rejected cases of Piracetam 400mg Tablets. M/s. Wilshire, Lahore.

Piracetam 400mg tablet formulations were deferred in 268th meeting of Registration Board for review by review committee. The review committee finalized their comments and the case was presented in 250th meeting of Registration Board with following comments

PIRACETAM 400MG TABLETS		
International availability	**Me too status**	**Remarks by review committee**
Not found in 400mg strength. Only 800 mg and 1200 mg strengths are available in MHRA.	CEREMIN 400mg tablet M/s Schazoo Laboratories	Not available in reference authorities. The daily dosage should begin at 7.2 g increasing by 4.8 g every three to four days up to a maximum of 24 g, in two or three sub-doses. Treatment with other anti-myoclonic medicinal products should be maintained at the same dosage. Depending on the clinical benefit obtained, the dosage of other such medicinal products should be reduced, if possible. (Ref. MHRA) N.B: (Review committee has not recommended the product for registration in 246th meeting of registration board. However, Registration Board discussed comments of stakeholders in 246th meeting and decided that Review Committee will review these comments for framing its final recommendation).
Decision: i. The formulation is not approved in reference drug regulatory agencies, hence the Board decided **NOT** to register the formulation in Pakistan. ii. Issuance of show cause notice for deregistration of already registered formulations.		

The formulation is available in France and registered by **ANSM** in the same strength and dosage form. The details of product registration are as follows

- **Brand Name:** PIRACETAM BIOGARAN 400 mg film-coated tablet
- **Market Authorization number:** 349 725-4: (60 coated tablets)
- **Status of authorization:** Valid
- **Composition**
  Active ingredient:
  Each film coated tablet contains Piracetam…….400 mg
  Additive:
  Core: Povidone K 30, magnesium stearate.
  Coating: WHITE OPADRY 03F28561 (macrogol 6000, titanium dioxide, talc, hypromellose), ethyl cellulose, dibutylsebacate.
- **Marketing Authorization holder:** BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes
- **Link for reference:**
  http://agence-prd.ansm.sante.fr/php/ecodex/extrait.php?specid=61732118
  (Accessed on 16-03-2017)

The following applications are hereby presented before the Board

S. No.	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition	Type of Form Initial date, diary Fee including differential fee	Remarks on the formulation (if any) including International status in stringent drug regulatory	Decision of previous DRB

		Pharmacological Group Finished product Specification	Demanded Price / Pack size	agencies / authorities Me-too status	
1.	M/s.Wilshire Laboratories, Lahore.	Q-Fix Tablets 400mg Each tablet contains:- Piracetam (I.N.N) …….400mg (Nootropics)	29-06-10 10's As per SRO		Referred to the review committee. (M-238) Rejected as the formulation is not approved by reference drug regulatory agencies (M-250)

Decision of 268th meeting: Keeping in view present approval status of above formulations in ANSM France the Registration Board approved the above formulation of Piracetam 400mg tablets. However, case of M/s Wilshire, Lahore will be deliberated in forthcoming meeting in presence of representative of Law & Justice Division.

Decision: - Registration Board does not accede to request of the firm as application has already been rejected in 250th meeting.

Case No.9 Registration of Drug(s), M/s. Jaens Pharmaceuticals Industries, Lahore.

Registration Board in its 237th meeting decided the following products of M/s. Jaens Pharmaceuticals Industries, Lahore. The Details are as under:-

S.No.	Name of Drug(s)	Demanded pack size & MRP	Demanded MRP	Decision of Registration Board.	Remarks
1.	Ja-cin Capsule Each Capsule contains:- Azithromycin…250mg	10's As per SRO		Confirmation of section from Licensing Section.	MHRA Approved

Firm has submitted following documents;

i. Form-5
ii. Photocopy of fee challan of Rs. 20,000/-
iii. Section approval letter

Decision: - Registration Board approved registration of above product in the name of M/s. Jaens Pharmaceuticals Industries, Lahore. Fee shall beverifi ed as per procedure adoptedby Registration Boardin .285th meeting

Case No.10 <u>Cancellation / Surrender of Psychotropic Registered Products of M/s. Danas Pharmaceuticals (Pvt.) Ltd., Islamabad.</u>

M/s. Danas Pharmaceuticals (Pvt.) Ltd; 312-Industrial Triangle, Kahuta Road, Islamabad has requested that they have to surrender the registration of their 16 following psychotropic products as they have already requested Licensing Division for conversion of their **Psychotropic Tablet Section into General Tablet Section-II** and obtain the letter No. F. 1-44/2003-Lic (Vol-I) dated 22nd August 2019 from DRAP regarding approval of revised layout plan. Detail of products is as under;

Sr. No.	Reg. No.	Product Name	Initial Reg. Date
1.	063237	Trancodan Tablet 1mg Each tablet contains:- Lorazepam USP … 1mg	11-05-2010

2.	063238	Trancodan Tablet 2mg Each tablet contains:- Lorazepam USP … 2mg	-do-
3.	063239	Prazodan Tablet 0.25mg Each tablet contains:- Alprazolam … 0.25mg	-do-
4.	063240	Prazodan Tablet 0.5mg Each tablet contains:- Alprazolam … 0.5mg	-do-
5.	063241	Prazodan Tablet 1mg Each tablet contains:- Alprazolam … 1mg	-do-
6.	063242	Brodan Tablet 1.5mg Each tablet contains:- Bromazepam … 1.5mg	-do-
7.	063243	Brodan Tablet 3mg Each tablet contains:- Bromazepam … 3mg	-do-
8.	063244	Brodan Tablet 6mg Each tablet contains:- Bromazepam … 6mg	-do-
9.	063245	Benzopine Tablet 2mg Each tablet contains:- Diazepam … 2mg	-do-
10.	063246	Benzopine Tablet 5mg Each tablet contains:- Diazepam … 5mg	-do-
11.	063247	Benzopine Tablet 10mg Each tablet contains:- Diazepam … 10mg	-do-
12.	063248	Danvin Tablet Each tablet contains:- Dextropropoxyphene HCl … 32.5mg Paracetamol …….. 325mg (BP Specifications)	-do-
13.	063249	Phenodam Tablet 30mg Each tablet contains:- Phenobarbitone …….. 30mg (BP Specifications)	-do-
14.	063250	Bupredan Sublingual Tablet 0.2mg Each tablet contains:- Buprenorphine as HCl …. 0.2mg (Danas Specifications)	-do-
15.	063251	Surgisafe Tablet 7.5mg Each tablet contains:- Midazolam …….. 7.5mg (Danas Specifications)	-do-
16.	063253	Opidan Tablet 25mg Each tablet contains:- Pentazocine as HCl …. 25mg (BP Specifications)	-do-

Firm has submitted an undertaking stating that no case is pending regarding above products in any court of law / Government organization.

Decision: - Registration Board acceded to request of the M/s. Danas Pharmaceuticals, Islamabad and decided to cancel registration products at Sr. No. 1-16.

Case No.11 Registration of Drugs, M/s. Jinnah Pharmaceuticals (Pvt.) Ltd, Multan.

Registration Board in its 238th meeting deferred the following products of M/s. Jinnah Pharma, Multan by way of contract manufacturing from M/s.English Pharma, Lahore. The details are given as under:-

Sr. No.	Reg. No.	Name of Drug (s) & Composition	Date of application, and Form.	Decision of 238th Meeting of DRB	Remarks
1.	044143	Tazobact 4.5gm Injection Each vial contains:- Piperacilline (as Sodium) ……..……4.0gm Tazobactum (as Sodium) …. 500mg (USP Specifications)	15-4-2013 Rs.50000/- Form-5	Deferred for registration letter	MHRA Approved Product was initially registered by way of contract manufacturing by Lowitt Pharma but not applied for extension
2.	044142	Tazobact 2.25gm Injection Each vial contains:- Piperacilline (as Sodium) ……...…….....2.0gm Tazobactum (as Sodium) …. 250mg (USP Specifications)	15-4-2013 Rs.50000/- Form-5	Deferred for registration letter	-do-

The firm has submitted that same products were registered on 26-09-2006 in their name on contract manufacturing by M/s. Lowitt Pharma. But due to some domestic issues they were not able to follow these products. Now they have requested to resubmit their applications in DRB which were for new toll manufacturing from M/s. English Pharma Lahore.

Firm has submitted following documents;

i. Form 5 along with receiving of application submitted on 15-04-2013
ii. Copy of Pay Order attested by concerned bank of Rs.50,000/- for each along with undertaking.
iii. Copy of agreement for contract manufacturing by M/s. English Pharma, Lahore for M/s. Jinnah Pharmaceuticals, Multan.
iv. Section approval of M/s. English Pharma, Lahore.

Decision: - Registration Board deferred for following;

a. .Confirmation of fee by Budget & Account s Division
b. .Registration status of already registered products
c. .Confirmation of submission of application of 2013

Case No.12 Registration of Drugs, M/s. Jinnah Pharmaceuticals (Pvt.) Ltd, Multan.

Registration Board in its 214th meeting decided the following registration applications of M/s. Jinnah Pharmaceuticals, Multan. The firm has requested that they have not yet received registration letter:-

S. No.	Name of Drug(s)	Demanded MRP	Application & fee details	Meeting reference	Remarks
1.	Malam DS Tablets. Each Tablet contains:- Artemether……..40mg Lumefantrine …… 240mg	1x10's	Rs. 260.00	Approved M-214	WHO Approved formulation Product is available in IP
2.	Malam Tablets. Each Tablet contains:-	10's	Rs. 130.00	Approved M-214	USFDA Approved

	Artemether……20mg Lumefantrine……120mg				Product is available in IP
3.	J-Zole Capsules. Each Capsule contains:- Omperazole ……20mg	14's	Rs. 155.00	Approved M-214	MHRA Approved Source of Pellets: Vision Pharma, Islamabad.
4.	J-Zome Capsules. Each Capsule contains:- Esomeprazole as Magnesium …….20mg	14's	Rs. 150.00	Approved M-214	MHRA Approved Source of Pellets: Vision Pharma, Islamabad.
5.	Zeel Capsules 30mg. Each Capsule contains:- Lansoprazole……30mg	10's	Rs. 150.00	Approved M-214	MHRA Approved Source of Pellets: Vision Pharma, Islamabad.
6.	Rispi Tablets 1mg. Each Tablet contains:- Risperidone……1mg	2x10's	Rs. 100.00	Approved M-214	**Film coated tablet approved in MHRA**
7.	Rispi Tablets 2mg. Each Tablet contains:- Risperidone……2mg	2x10's	Rs. 190.00	Approved M-214	**Film coated tablet approved in MHRA**
8.	Olzan Tablets 10mg. Each Tablet contains:- Olanzapine…….10mg	10's	Rs. 150.00	Approved M-214	MHRA Approved
9.	J-Mox Tablets. Each Tablet contains:- Moxifloxacin as HCl……...400mg	10's	Rs. 400.00	Approved M-214	USFDA Approved Product is available in USP
10.	J-Pan Tablets. Each Tablet contains;- Pantoprazole as Na ……..40mg	14's	Rs. 600.00	Approved M-214	**Delayed release tablet is approved in USFDA**
11.	Ketojan Tablets 1mg. Each Tablet contains:- Ketotifen as Fumarate…….1mg	3x10's	Rs. 80.00	Approved M-214	Health Canada Approved
12.	J-Meb Tablet. Each Tablet contains:- Mebevarine as HCl……..135mg	3x10's	Rs. 160.00	Approved M-214	TGA Approved
13.	Jeozine Tablets 5mg Each tablet contains:- Levocetirizine Dihydrochloride … 5mg	10's	As per SRO	Approved subject to HVAC and completion of files. M-218	**Film coated tablet approved in MHRA**
14.	Perilol Tablets Each tablet contains:- Atenolol ……. 100mg	2x10's	Rs.90.00 Per Pack	Approved subject to HVAC and completion of files. M-218	USFDA Approved
15.	Perilol Tablets Each tablet contains:- Atenolol …… 50mg	2x10's	Rs.45.00 Per Pack	Approved subject to HVAC and completion of files. M-218	USFDA Approved

16.	J – Pril Tablets Each tablet contains:- Captopril …… 25mg	2x10's	Rs.60.00 Per Pack	Approved subject to HVAC and completion of files. M-218	USFDA Approved
17.	J Pril Tablets Each tablet contains:- Captopril ……. 50mg	2x10's	Rs.12.00 Per Pack	Approved subject to HVAC and completion of files. M-218	USFDA Approved
18.	J- Fer Plus Tablets Each tablet contains:- Iron (III) hydroxyl polymaltose Complex Eq. to Elemental Iron ……..100mg Folic acid USP … 0.35mg	3x10's	Rs.200.00 Per Pack	Approved subject to HVAC and completion of files. M-218	Iron preparations are not considered as drug by various reference regulatory authorities
19.	J- Fer Tablets Each tablet contains:- Iron (III) hydroxyl polymaltose Complex Eq. to Elemental Iron …….100mg	3x10's	Rs.170.00 Per Pack	Approved subject to HVAC and completion of files. M-218	Iron preparations are not considered as drug by various reference regulatory authorities
20.	Melocam Tablets Each tablet contains:- Meloxicam …… 15mg	1x10's	Rs.60.00 Per Pack	Approved subject to HVAC and completion of files.	USFDA Approved
21.	Melocam Tablets Each tablet contains:- Meloxicam ……. 7.5mg	1x10's	Rs.60.00 Per Pack	Approved subject to HVAC and completion of files.	USFDA Approved

Firm has submitted duplicate dossier along with differential fee of Rs.12000/- dated 27-08-2020.

Decision: Registration Board decided as under;

i. **Approved the registration of products at Sr. No. 1-5, 8, 9, 11, 12 & 14-21. Fee of Rs. 8000/- shall beverifi ed as per procedure adopted by Registration Boardin 285th .meeting**

ii. **Deferred the products at Sr. No. 6, 7, 10 & 13 for submission of fee.**

Case No.13 Registration of Drug(s) M/s. Shaigan Pharmaceuticals (Pvt.) Ltd; Rawalpindi.

Registration Board in its 291st decided to approve registration of TIKANOX (Ticagrelor) 30mg & 90mg Tablets by M/s. Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months:-

Sr. No.	Name of Firm	Product Name
1.	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-60 Tablets Each Film coated tablet contains: Ticagrelor …..... 60mg Platelet activation inhibitor Manufacturer's specifications
2.	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-90 Tablets Each Film coated tablet contains: Ticagrelor …..... 90mg

		Platelet activation inhibitor Manufacturer's specifications

After discussion with PEC, it is clarified that firm has submitted stability of Ticagrelor 60mg & 90mg and due to typographical error, it was written as Ticagrelor 30mg & 60mg in decision of the minutes while the product is available only in strengths of 60mg & 90mg internationally. Firm has also submitted copies of receiving of registration applications which shows that firm had submitted applications for registration of Ticagrelor 60mg & 90mg. Accordingly, registration letter was issued for the correct strengths i.e, Ticagrelor 60mg & 90mg.

Decision: Registration Board noted the information

Case No.14 M/s Ambrosia Pharmaceuticals, Islamabad.

M/s Ambrosia Pharmaceuticals, Islamabad have requested for correction in brand name, pack and MRP of their registered product with following details.

S. No.	Reg. No.	Existing Name of drug(s) with formulation	Demanded Corrections	Existing Pack & MRP	Demand pack & MRP	Decision of 9th PRVC
I	II	III	IV	V	VI	VII
1.	040815	Amrotose comples syrup Each 5ml contains: Iron (III) Hydroxide Polymaltose complex …..…50mg	Amrotose **Complex** Syrup Each 5ml contains: Iron (III) Hydroxide Polymaltose complex ……50mg	Rs.70/120ml	Rs.133/120ml	The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to defer the request of M/s Ambrosia Pharmaceuticals, Islamabad for submission of copy of form-5 for verification of brand name and decided to advise the firm to apply in C & P Division for additional pack of 120ml.

Now the firm has submitted copy of Form-5 which shows that firm has applied with the brand name of **Polytose complex syrup**.

Remarks of the section:

The approved price for Iron (III) Hydroxide Polymaltose complex 50mg/5ml syrup is Rs.70/60ml. The demanded price i.e. Rs.133/120ml is not available in pricing minutes.

The firm has submitted following documents:

i. Copy of registration letter dated 13-07-2005
ii. Last Renewal applied: 10-07-2015
iii. NOC of CRF clearance valid till 31-12-2018

Decision of Chairman RB taken in 11th meeting of PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to approve the request of M/s Ambrosia Pharmaceuticals, Islamabad for issuance of corrigendum in brand name of above product while for correction of pack and MRP, the case is referred to Registration Board.

Decision of RB taken in its 284th meeting: Registration Board deferred the request of the firm for confirmation of demanded MRP and pack size from record.

Now the record has been checked and found that firm has demanded Rs.98.80 for 60ml pack.

Registration Board in its 286th meeting decided to refer the case to C & P Division.

Latterly it was discussed that firm's demanded MRP/Pack size is Rs.98.80/60ml as mentioned in 286th meeting. Firm has also submitted an undertaking regarding demanded MRP/Pack size. Accordingly, case is re-submitted for consideration of Registration Board.

Registration Board in its 295th meeting deferred the case for confirmation of demanded MRP and pack size from registration dossier.

The firm has submitted copy of receiving of registration application submitted on 03-12-2004 confirming that the firm had applied "**Polytose complex syrup**" containing Iron (III) Hydroxide Poly Maltose Complex 10mg/1ml in **60ml bottle packing**.

Decision: Registration Board approved correction of pack size from 120ml to 60ml.

Case No.15 Correction of Pack size of Drug(s) of M/s. Bajwa Pharma, Lahore.

Registration Board in its 282nd meeting approved the following product of M/s. Bajwa Pharma, Sheikhupura and it was not processed due to packing clarification.:-

S.No.	Name of Firm	Name of Drug(s) with composition	Demanded MRP	Approved MRP	Decision of Registration Board.
1.	M/s Bajwa Pharmaceuticals (Pvt) Limited, 36 Km, Lahore-Gujranwala Road, Khori District, Sheikhupura	Keto-baj Injection 1ml Each ml ampoule contains: Ketorolac Tromethamine……..30mg (USP Specification)	1x 5ml ampoules & as per PRC	Rs.430.00/ 5'sx1ml	Approved with U.S.P. specifications.

The firm submitted request alongwith fee of Rs.5000/- for correction of pack size from "1x 5ml" to "**5'sx1ml**" which have been incorporated in relevant file at pages 310-311/cor.

Registration Board in its 293rd meeting deferred the request of the firm for submission of differential fee.

The firm has submitted remaining fee amounting Rs.15000/- for this purpose and requested for correction of pack size.

Decision: Registration Board deferred for updated GMP status.

Case No.16 Registration of M/s. N.B.S Pharma, Lahore

Following products of M/s N.B.S Pharma, Lahore were considering 215th meeting of registration board and decided as follows.

Sr.No	Name of Drug	Decision
1.	Povidone-1 Solution Each 100ml contains:- Povidone Iodine USP 7.5gm equivalent to 0.75% available iodine (USP)	Approved subject to the submission of the last Inspection report.

It is submitted that the above cases were discussed in 215th meeting of registration board and decision of the board has been reflected in the above table. The firm has now submitted the differential free of Rs. 12000/- and submitted the inspection report dated 12.11.2014. which shows details of the section as under:-

External Preparation Section:-

This section comprised of preparation and filling rooms, equipped with preparation vessels of different sizes. Silver san mixer and filling machines was installed HVAC system was provided in this area and was functional at the time of inspection. Re-packing area was equipped with filling machine and different size vessels. HVAC system was installed production area furnish with epoxy.

Registration Board in its 260th meeting deferred the case for GMP status of the firm and confirmation of section either from Licensing division or from panel / renewal inspection report.

The firm has submitted copy of inspection report 20-09-2019 with conclusion that the firm has rectified most of the shortcomings pointed out during last inspection. The panel recommends that M/s. N.B.S Pharma, Lahore may be allowed to resume the production in all sections.

Mr. Ajmal Sohail Asif Area FID vide letter No. 15075/2016-DRAP (L-II) dated 17-10-2016 clarified that the firm has approved external preparation section and is already manufacturing Povidone I Solution, (Povidone Iodine SP. 10gm eq. to 1% Iodine) under Reg. No. 025552

Decision: Registration Board deferred the case for confirmation of section approval from Licensing division.

Case No.17 Registration of Drug(s) M/s. GT Pharma (Pvt.) Ltd; Lahore.

Registration Board in its 256th meeting approved the following product of M/s. GT Pharma (Pvt.) Ltd; 713-Sundar Industrial Estate, Sundar Raiwind Road, Lahore:-

Sr. No.	Product Name	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	Me-too and RRA reference	Decision of 256th meeting
1.	Cheliron Capsules Each Capsule contains Iron Hydroxide polymaltose Complex 150mg Antianemia (Manufacture Specification)	Form 5 Rs. 20,000/- vide Dy. No. 2684 dated 11-12-2015 Pack size of 3 x 10's / as per price fixed by Government	*v.Niferex* UCB Brussels, Belgium. FERRICURE S.J. & G. FAZUL ELLAHIE (PVT) LTD.	Approved

Firm has submitted that they had applied for registration of Cheliron Capsule for registration that is approved in meeting 256th with mistakenly written Iron Polymaltose Complex instead of Polysaccharide Iron Complex. Firm has requested to correct formulation from **Iron Polymaltose Complex** to **Polysaccharide Iron Complex**. Firm has submitted following documents;

i. Form-5 (Duplicate dossier)
ii. Fee submission of Rs.20,000/- for correction.

Decision: Registration Board acceded to request of the firm and approved the correction of formulation as under;

Cheliron Capsules
Each Capsule contains
Polysaccharide Iron Complex … 150mg

Case No.18 Change of Brand name of Product of M/s. CCL Pharmaceuticals, Lahore.

Registration Board in its 282nd meeting approved the following products of M/s. CCL Pharmaceuticals, Lahore as per following details:-

465.	Name and address of manufacturer / Applicant	CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Syrup 250mg/5ml Each 5ml contains:- Carbocysteine….250mg
	Diary No. Date of R& I & fee	
	Composition	Dy No. 476, 29-01-2015; PKR 20,000/-, 28-01-2015
	Pharmacological Group	(mucolytic agent)
	Type of Form	Form 5
	Finished product Specification	As per Innovator
	Pack size & Demanded Price	120mL/ As per brand leader
	Approval status of product in Reference Regulatory Authorities.	Mucodyne syrup 250mg/5ml by Lexon (MHRA Approved)
	Me-too status	Rhinathiol syrup by Sanofi Aventis
	GMP status	Last inspection report dated 8-3-2017 confirms satisfactory compliance to GMP
	Previous remarks of the Evaluator.	Firm has provided specifications of the innovator and also the commitments to conduct validation of analytical method. The submitted specifications (claimed to be of innovator) contains tests for physical description, pH, taste, odor, identification and assay while according to MHRA and Irish assessment report the specification of mucodyne should be as per pharmacopoeial monograph for 'Liquid preparations for oral use'. The general monograph for liquid preparations for oral use contains tests for fill volume, uniformity of mass and uniformity of dosage units as well.
	Previous decision(s)	Deferred for following submission (M-269): ● Change of brand name as the same is registered for different active ingredient ● Latest GMP inspection report conducted within 1 year ● Clarification regarding the submitted innovator's specification as they do not contain test of general monograph for "liquid preparations for oral use" including fill volume, uniformity of mass and uniformity of dosage units as mentioned in the Irish and MHRA assessment report. ● Deferred for further deliberation for brand name of Pulmonol M for applied formulation (M-274). ● Registration Board deferred the case and advised PEC to present the case with detailed composition of already registered Pulmonol brands. Moreover Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-281).
	Evaluation by PEC ● Firm has stated that "Pulmonol" is our registered trademark having TM No. 085475 dated (18-02-1985) in class 5 under section 33 of the Trade mark ordinance 2001, and following products are already registered in different composition and indicated for wide range of indications of upper respiratory tract disorders which are in line extension of Pulmonol range: i. Pulmonol syrup, Reg.# 00874 ii. Pulmonol Flu Syrup, Reg.# 068109 iii. Pulmonol DM Syrup, Reg.# 068110 iv. Pulmonol Junior Syrup, Reg.# 068111 v. Pulmonol CF Tablets, Reg.# 023982	

- A similar case of change of brand name was presented n 263rd meeting of Registration Board wherein M/s. CCL Pharmaceuticals (Pvt) Ltd, Lahore had requested for change of brand name of their following product:

Names of Drug(s) with formulation	Reg. No.	New proposed names
Epinol CF Tablet Each tablet contains: Paracetamol……500mg Pseudoephedrine HCl….60mg Chlorpheniramine Maleate..4mg	023982	Pulmonol CF Tablet

Registration Board deliberated that suffix of brand name is different, thus the Board approved request of firm for change of brand name from Epinol CF Tablet to Pulmonol CF Tablet.

- The firm described that Pulmonol is their flagship brand name which covers the product indicated in disorder of upper respiratory tract especially cough and cold in different combination. Furthermore as per business strategy and marketing norms one brand name can be used for minutely different formulations of same category of products e.g Hydryllin syrup, Hydryllin DM syrup, Hydryllin Day syrup etc.
- Firm has submitted revised finished product specifications including test of filled volume, deliverable volume & Uniformity of dosage unit.
- Copy of Panel inspection conducted on 20-04-2018 & 24-04-2018 concluded that the firm was found to be operating at a satisfactory level of GMP compliance.
- The firm has submitted that we already have following four products registered with brand name Pulmonol in different composition and indicated for wide range of indications for upper respiratory tract disorders especially cough & cold. The detailed compositions of pulmonol brand names is as follows:

Brand Name	Composition
Pulmonol Syrup	Each 5ml contains: Chlorpheniramine Maleate BP …...5mg Terpin Hydrate USP …… 10mg Pot. Bicarbonate BP ……. 0.1mg Ammonium Chloride BP …….. 25mg Tr. Senega BP …….. 0.05ml Menthol BP …….. 1mg Aminophylline Ph. Eur. …….. 32mg Pot. Guaiacol Sulphate USP ……. 5mg Pot. Citrate BP ……... 0.1mg
Pulmonol Flu Syrup	Each 5ml Contains: Chlorpheniramine Maleate ….……1mg Pseudoephedrine HCl…….. 15mg Paracetamol …… 160mg Dextromethorphan HBr …….. 7.5mg
Pulmonol DM Syrup	Each 5ml Contains: Pseudoephedrine HCl …… 30mg Dextromethorphan HBr ……. 10mg
Pulmonol Junior Syrup	Each 5ml Contains: Promethazine HCl ……. 1.5mg Pholcodine …… 1.5mg Absolute Alcohol …… 3.8%
Pulmonol CF Tablet	Each tablet contain: Paracetamol ……..… 500mg Pseudoephedrine HCl ……60mg Chlorpheniramine Maleate ….. 4mg

Decision: Registration Board did not accede to firm's request for assigning brand name of "Pulmonol" for applied formulation because it can lead to medication errors due to different compositions. Hence Registration Board approved the applied formulation with change of brand name.

466.	Name and address of manufacturer / Applicant	CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Capsule 375mg Dy No. 475, 29-01-2015; PKR 20,000/-, 28-01-2015 Each capsule contains:- Carbocysteine….375mg
	Diary No. Date of R& I & fee	
	Composition	
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	30's/ As per Brand leader
	Approval status of product in Reference Regulatory Authorities.	Mucodyl Capsule by Sanofi (MHRA Approved)
	Me-too status	Rhinathiol Capsule by Sanofi
	GMP status	Last inspection report dated 21-03-2016 recommends the grant of renewal of DML
	Previous remarks of the Evaluator.	● Firm has provided specifications of the innovator without detailed method of analysis and also the commitments to conduct validation of analytical method. The submitted specifications (claimed to be of innovator) contains dissolution test with specification NLT 70% (Q) in 30 minutes
	Previous decision(s)	Deferred for following (M-269): ● Change of brand name as the same is registered for different active ingredient ● Latest GMP inspection report conducted within 1 year ● Clarification regarding the submitted innovator's specification as dissolution test parameters Q mentioned in the reply to letter is NLT 70%, while the value of Q mentioned in original dossier was NLT 80% in 30 minutes Deferred for following (M-271): ● Word "Pulmonol" is not stated on copy of trade mark certificate submitted. Clarification is required in this regard. ● Clarification from R-V section regarding approval of "Pulmonol" brand name for various formulations.
	Evaluation by PEC: ● Firm has submitted following: ● Copy of Panel inspection conducted on 20-04-2018 & 24-04-2018 concluded that the firm was found to be operating at a satisfactory level of GMP compliance. ● Clarification that they regret for the typographical mistake as the original value of Q is NLT 80% in 30 minutes. ● Moreover firm has stated that "Pulmonol" is our registered trademark having TM No. 085475 dated (18-02-1985) in class 5 under section 33 of the Trade mark ordinance 2001, and following products are already registered in line extension of Pulmonol range: vi. Pulmonol Cough syrup, Reg.# 00874 vii. Pulmonol Flu Syrup, Reg.# 068109 viii. Pulmonol DM Syrup, Reg.# 068110 ix. Pulmonol Junior Syrup, Reg.# 068111 x. Pulmonol CF Tablets, Reg.# 023982 In light of above details the Firm has requested to allow brand name of Pulmonol Capsule 375 mg in line extension of their Pulmonol range **Decision: Registration Board did not accede to firm's request for assigning brand name of "Pulmonol" for applied formulation because it can lead to medication errors due to different compositions. Hence Registration Board approved the applied formulation with change of brand name.**	

Now the firm has submitted that the brand name Pulmonol is a household name in the respiratory tract disorder and currently covering cough, cold and sore throat indications. They have requested that the brand name "**Pulmonol-M"** is a line extension of umbrella brand name because of mucolytic effect of Carbosysteine falling under same category of respiratory tract disorders.

Registration Board in its 291st meeting deferred the request of the firm for scientific justification.

Now firm has requested for withdrawal of their request of 291st meeting regarding line extension of umbrella brand name and requested to issue registration letter with change of brand name.

Decision: Registration Board acceded to request of the firm and decided to process the case as per decision of 282nd meeting.

Case No.19 Deferred product of M/s. Shrooq Pharmaceuticals (Pvt.) Ltd, Lahore

Registration Board in its various meetings decided the following products of M/s. Shrooq Pharmaceuticals (Pvt.) Ltd; 21-Km, Feruz Pur Road, Lahore. Details are given as under:-

S.No	Brand Name/Label claim	Demanded Pack size	Demanded Price	Decision of RB	Remarks
1.	Valrox Syrup Each 5ml contains:- Divalproex Sodium…….500mg (Anti-epileptics)	60ml	As per SRO	Approved. The Board advised to submit finished product specifications. M-238	Firm has now requested to change strength of formulation as **Each 5ml contains:- Divalproex Sodium…..250mg**
2.	Cegrel-Ap Tablet Each tablet contains:- Clopidogrel (Bisulphate)…75mg Aspirin……...150mg	10's	As Per SRO	Deferred for latest GMP report M-263	Firm has now requested to change strength of formulation as **Each tablet contains:- Clopidogrel (Bisulphate)… 75mg Aspirin…… 75mg**
3.	Airvent Tablet 8mg Each tablet contains Montelukast Sodium……. 8mg Leukotriene receptor antagonist	7's	Rs.155	Deferred for confirmation of the applied formulation in references regulatory authorities M-265	Firm has now requested to change strength of formulation as **Each chewable tablet contains Montelukast Sodium……. 4mg**

Firm has submitted following documents;

i. Form 5.
ii. Evidence of fee of Rs.8000/- (Photocopy) along with fresh submission of Rs.12000/- for each product.
iii. cGMP certificate based upon evaluation conducted on 29-01-2019.

Registration Board in its 291st meeting decided deferred the products at Sr. No. 4-6 for submission of fee.

The firm has submitted fee of Rs.5000/- for each product and requested to issue registration letter.

Decision: Registration Board deferred for submission of complete case including RRAs status of previously applied formulations.

Case No.20 Registration of Drug(s) M/s. Candid Pharmaceuticals, Lahore.

M/s. Candid Pharmaceuticals Opp. Eden Avenue Extension Airport Road, Lahore was granted the registration of following products:-

Old Reg. numbers issued			
S.No.	**Old Reg. No.**	**Name of Drug(s) & Composition**	**Remarks**
1.	028384	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 250mg	The firm was granted registration vide letter No.F.3-3/2002-Reg-II (M-171) dated 21-08-2002 but the contract manufacturing condition was not mentioned initial letter of registration. Brand name was changed to Efxone vide letter dated 05-10-2002. These products contract manufacturing permission was extended vide letter No.F.3-1/2008-Reg-II-South(M-212) dated 18-09-2008 till 30-06-2010.
2.	028385	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 500mg	
3.	028386	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 1gm	
New Reg. numbers issued in 275th meeting			
4.	087354	Efxone Injection 250mg IV Each vial contains: Ceftriaxone (as sodium)..…….250 mg (USP Specifications)	The firm was granted registration of these products vide letter No.F.8-11/2017-Reg-III(M-275) dated 29-12-2017 after the approval of Ceph. Injectable section by Licensing Division.
5.	087355	Efxone Injection 250mg IM Each vial contains: Ceftriaxone (as sodium)…….250 mg (USP Specifications)	
6.	087356	Efxone Injection 1gm IV Each vial contains: Ceftriaxone (as sodium)……1000mg (USP Specifications)	

Registration Board in its 275th meeting approved transfer of registration from contract manufacturing to their own facility but due to typographical error firm was granted registration of Ceftriaxone 250mg Injection (IM) (Reg.No.087355) instead of Ceftriaxone 500mg Injection (IV). The firm has requested to correct the strength/rout of administration from "Efxone (Ceftriaxone) 250mg Injection IM (Reg.No.087355) to "Efxone (Ceftriaxone) 500mg Injection IV (Reg.No.087355).

Firm has also provided copies of application receiving which shows that the firm had applied "Efxome (Ceftriaxone) 250mg & 500mg Injection IV.

Registration Board in its 295th meeting deferred for confirmation of manufacturing status of the product.

The firm has summited undertaking that they are not manufacturing the product "Efxone Injection 250mg IM" (Reg.No.087355) since grant of its registration dated 29-12-2017 due to typographical error as stated above.

Decision: Registration Board acceded to request of the firm and approved correction of strength/route of administration as under;

Efxone Injection 500mg IV
Each vial contains:
Ceftriaxone (as sodium)…….500 mg

Case No.21 Request of M/s. Don Valley (Pvt.) Limited, Lahore for import of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s Don Valley (Pvt.) Lahore has requested for permission to import a controlled drug substance for developing their products and stability study. Details are as under:

1. **Phenobarbital**

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Phenobarbital 30mg Tablet**	1000gm	Nantong, Jinghua China	B.P Specification
	Total	**1000gm**		
2.	**Phenobarbital Working Standard**	200mg		
3.	**Phenobarbital impurity A CRS**	100mg		
4.	**Phenobarbital impurity B CRS**	100mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Phenobarbitone 30mg Tablet**	Phenobarbitone	30mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	990.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	1000.00

2. **Lorazepam**

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Lorazepam 1mg Tablet**	43gm	Centaur Pharmaceuticals (Pvt.) Ltd India	B.P Specification
	Lorazepam 2mg Tablet	66gm		
	Total	**109gm**		
2.	**Lorazepam Working standard**	400mg		
3.	**Impurity E**	100mg		
4.	**Lorazepam EPCRS for system suitability**	100mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. **Lorazepam 1mg**

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required

1.	**Lorazepam 1mg Tablet**	**Loraze pam**	1mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	33.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	43.00

ii. Lorazepam 2mg

S. No.	**Product**	**API**	**Mg/Tab**	**No. of Tab/batch**	**No. of batches**	**Quantity of API required**		
1.	**Lorazepam 2mg Tablet**	**Loraze pam**	2mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	66.00	--	66.00

3. Methylphenidate HCl

S. No.	**PRODUCT NAME**	**QUANTITY REQUIRED**	**SOURCE**	**Product Specification**
1.	Methylphenidate HCl 10mg Tablet	340gm	Centaur Pharmaceuticals (Pvt.) Ltd India	B.P Specification
	Total	**340gm**		
2.	Methylphenidate HCl working standard	600mg		
3.	Methylphenidate Impurity C	100mg		
4.	Methylphenidate Impurity mixture	100mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	**Product**	**API**	**Mg/Tab**	**No. of Tab/batch**	**No. of batches**	**Quantity of API required**

1.	**Methylphenidate HCl 10mg Tablet**	Methylphenidate HCl	10mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	330.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	340.00

4. Pentazocine HCl

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	Pentazocine HCl 25mg Tablet	835gm	Sun Pharmaceuticals, India	B.P Specification
	Total	**340gm**		
2.	Pentazocine HCl Working Standard	200mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	Pentazocine HCl 25mg Tablet	Pentazocine HCl	25mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	825.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	835.00

5. Diphenoxylate HCl

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	Diphenoxylate HCl 2.5mg Tablet along with Atropine Sulphate	92.5gm	RPG Life Science Ltd, India	USP Specification
	Total	**92.5gm**		
2.	Diphenoxylate HCl working standard	200mg		

3.	Diphenoxylate HCl Related compound A	5mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Diphenoxylate HCl 2.5mg Tablet**	Diphenoxylate HCl	2.5mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	82.5	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	92.5

6. Diazepam

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Diazepam 5mg Tablet**	175gm	Centaur Pharmaceuticals (Pvt.) Ltd India	B.P Specification
2.	**Diazepam 10mg Tablet**	330gm		
	Total	**505gm**		
3.	**Diazepam Working standard**	400mg		
4.	**Diazepam CRS for system suitability**	10mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Diazepam 5mg

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Diazepam 5mg Tablet**	Diazepam	5mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3**	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	165.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	175.00

				(10,000 tablets)				

ii. Diazepam 5mg

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Diazepam 10mg Tablet**	Diazepam	10mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	330.00	--	330.00

7. Buprenorphine

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Buprenorphine Tablet**	17.115gm	Micro Orgo Chemicals India	B.P Specification
	Total	**92.5gm**		
2.	**Buprenorphine HCl working standard**	200mg		
3.	**Buprenorphine HCl CRS for system suitability**	100mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Buprenorphine 0.2mg Tablet**	Buprenorphine Hydrochloride	0.2mg	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	7.115	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	17.115

8. Zolpidem

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Zolpidem Tartrate Tablet**	340g	Centaur Pharmaceuticals (Pvt.) Ltd India	B.P Specification
	Total	**340g**		
2.	**Zolpidem Tartrate Working Standard**	200mg		
3.	**Zolpidem Related Compound A**	15mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Zolpidem Tartrate 10 mg tablet**	Zolpidem Tartrate	10.0	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	330.00	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	340.00

9. Alprazolam

S. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE	Product Specification
1.	**Alprazolam 0.5mg Tablet**	26.50gm	Centaur Pharmaceuticals (Pvt.) Ltd India	B.P Specification
2.	**Alprazolam 1.0mg Tablet**	33.00gm		
	Total	**59.50gm**		
3.	**Alprazolam Working Standard**	400mg		
4.	**Alprazolam Related compound A**	30mg		
5.	**2-Amino-5-chlorobenzophenone**	30mg		
6.	**Chlordiazepoxide Related Compound A**	30mg		

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Alprazolam 0.5mg

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Alprazolam 0.5mg tablet**	Alprazolam	0.5	**Batch size for trial batch** (1,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g

				Batch size of Stability Batch No.1 (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial batches (3) Stability batches (3)	16.50	For chemical testing: 5.00 Retention Sample: 5.00 Total: 10.00	26.50

ii. Alprazolam 1.0mg

S. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	**Alprazolam 1.0mg tablet**	Alprazolam	1.0	**Batch size for trial batch** (1,000 tablets) **Batch size of Stability Batch No.1** (10,000 tablets) **Batch size of Stability Batch No.2** (10,000 tablets) **Batch size of Stability Batch No.3** (10,000 tablets)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	33.00	--	33.00

Decision: Registration Board approved the allocation of controlled drug substances i.e i) Phenobarbital ii) Lorazepam iii) Methylphenidate HCl iv) Pentazocine HCl v) Diphenoxylate HCl vi) Diazepam vii) Buprenorphine viii) Zolpidem ix) Alprazolam for trial, development & stability batches of above mentioned products. The Board further advised the firm to maintain records of used substances and waste materials having above APIs will be destroyed after approval of Controlled Drug Division, DRAP.

VETERINARY

Case.No.01:- REQUEST OF M/S. D-MAARSON PHARMACEUTICALS, RAWAT, ISLAMABAD REGISTRATION OF DRUGS.

M/s. D-Maarson Pharmaceuticals, Rawat, Islamabad has requested for registration of following veterinary products for local manufacture in their name and cancellation of same from the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Size(s)	Initial Date of Registration
1.	102083	Ivoron Drench Oral Liquid Each 100ml contains:- Ivermectin……2.4mg (As per Innovator's Specification)*	100ml 250ml 500ml 1Litre 2.5Litre	30-04-2020
2.	102084	Tenex 19.5% Drench Each 100ml contains:- Tricabendazole……..12gm Levomizole (HCl)…..…....7.5gm Sodium Selenite……0.035gm Cobalt Chloride…..…..0.075gm (As per Innovator's Specification)*	100ml 250ml 500ml 1Litre 2.5Litre	-do-
3.	102085	Ketojet Injection Each ml contains:- Ketoprofen……100mg (BP Specifications)	50ml	-do-
4.	102155	Cyanavit-12 Injection Each ml contains:- Vitamin B- 12……..1000mcg (As per Innovator's Specification)*	50ml	-do-
5.	102156	Furason Injection 50mg Each ml contains:- Furosemide……50mg (USP Specifications)	50ml	-do-
6.	102157	Enropro 20% Injection Each ml contains:- Enrofloxacin……..…200mg (As per Innovator's Specification)*	100ml	-do-
7.	102159	Redox-34 Injection Each 100ml contains:- Nitroxynil…….34gm (As per Innovator's Specification)*	50ml	-do-

8.	102160	Sporex Drench Each ml contains:- Sulphadaizine……..35.5mg Neomycin Sulphate.……1.8mg Pectin……...7.1mg Vitamin B……0.5mg Sulphadimidine……..28.4mg HyosinMethylbromide…..0.04mg Kaoline……103.3mg Vitamin B2……..…0.22mg (As per Innovator's Specification)*	100ml 250ml 500ml 1000ml	-do-
9.	102256	Atrapin Injection Each ml contains:- Atropine Sulphate……1mg (USP Specifications)	50ml	22-06-2020

M/s. D-Maarson Pharmaceuticals, Rawat, Islamabadhas deposited the required fee Rs. 20,000 x 9 = 180,000 and submitted following supporting documents:-

(i) Original NOC **dated 06-05-2020& 07-07-2020**from M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.
(ii) Copy of initial registration letters.
(iii) Copy of Drug Manufacturing License.
(iv) GMP inspection report conducted on 13-11-2018. The panel recommended the DML No.000744 (Formulation) for the following sections.

(a) Oral Powder Section (Veterinary).
(b) Oral Liquid Section (Veterinary).
(c) Bolus Section (Veterinary).
(d) Liquid Vial Injectable Section (Veterinary).

(v) Applications on Form 5.
(vi) Undertaking.

Decision:- Registration Board decided as follow;

a. Approved the cancellation of registration of above mentioned products from the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.
b. Approved the registration of above mentioned products (Sr.No.2-9 of above table) in the name of M/s. D-Maarson Pharmaceuticals, Rawat, Islamabad.
c. Deferred product at Sr. No.1 for Generic status confirmation/standardization of formulation with requisite form and fee.

Case.No.02:- REQUEST OF M/S. NAWAL PHARMACEUTICALS, TAXILA REGISTRATION OF DRUGS.

M/s. Nawal Pharmaceuticals, Taxila has requested for registration of following veterinary product for local manufacture in their name and cancellation of same from the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Size(s)	Initial Date of Registration
1.	102158	Toldem Injection Each 100ml contains:- Toldimfos Sodium……..20gm Vitamin B-12……5mg (As per Innovator's Specification)*	50ml	30-04-2020

M/s. Nawal Pharmaceuticals, Taxila Islamabad has deposited the required fee Rs. 20,000/- and submitted following supporting documents:-

(i) Original NOC **dated 06-05-2020** from M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.
(ii) Copy of initial registration letter.
(iii) Copy of Drug Manufacturing License.
(iv) GMP inspection report conducted on 29-10-2018DML No.000735 (Formulation).
(v) Copy of approved section.
(vi) Applications on Form 5.
(vii) Undertaking.

Decision:- Registration Board decided as follow;

a. **Approved the cancellation of registration of above mentioned product (of above table) from the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.**
b. **Approved the registration of above mentioned product (of above table) in the name of M/s. Nawal Pharmaceuticals, Taxila Islamabad.**

Case.No.03:- REQUEST OF M/S. REGENT LABORATORIES, KARACHI REGISTRATION OF DRUGS.

M/s. Regent Laboratories, Karachi has requested for registration of following veterinary product for local manufacture in their name and cancellation of same from the name of M/s. Epla Laboratories (Pvt) Ltd., Karachi& M/s. Spencer Pharma (Pvt) Ltd., Karachi.

S. No.	Reg. No.	Name of Drug(s)/ Composition as Registration letter	Already Approved Pack Size(s) as per registration letter.	Initial Date of Registration, Variation/ Renewal Status

1.	022772	Vitapol Powder Each gm powder contains:- Vitamin A USP…….20,000 Units Vitamin D3……..4,000 Units Vitamin E eq. to…...1.6 Units (8mg) Thiamine HCI……...1.25mg Pyridoxine HCI……..6mg Ascorbic Acid ……..10mg Nicotinic Acid…….....100mg Calcium D Pantothenate……...30mg Folic Acid……...2mg Cyanocobalamin……..30mg Riboflavin 5 Phosphate Sodium……..20mg Vitamin K3…….9mg	100gm 300gm 1000gm	**18-08-2004** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on **18-08-2004** **16-08-2019**
2.	025706	Zorox Drench Each ml contains:- Oxfendazole B.P……22.65mg Oxyclozanide B.P……62.2mg	100ml 250ml 500ml 1000ml	**22-05-2000** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on **18-08-2004** **07-08-2019**
3.	025707	Zorox Gold Drench Each ml contains:- Oxfendazole B.P……22.65mg Oxyclozanide B.P……62.2mg Selenium (as Sodium Salt)…...0.5mg Cobalt (as Cobalt Sulphtate)..1.67mg	100ml 250ml 500ml 1000ml	**22-05-2000** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on **18-08-2004** **07-08-2019**
4.	022774	Trizine Oral Suspension Contains:- Trimethoprim B.P…….8% w/v Sulphadiazine B.P……40% w/v	50ml 200ml	**22-05-2000** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. EplaLaboratories (Pvt) Ltd.,

				Karachi on **18-08-2004** **07-08-2019**
5.	022771	Coxidar Liquid Contains:- Diaveridine B.P……0.6% Sulphaquinoxaline B.P……...2.56%	100ml 450ml	**14-04-1999** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on **18-08-2004** **07-08-2019**
6.	023451	Tysin Powder Contains:- Tylosin Tartrate B.P…….5% w/w Erythromycin Thiocyanate...6% w/w **Furaltadone Hydrochloride**……...15% w/w	250gm 500gm	**02-06-1999** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on **21-10-2004** **07-08-2019**
7.	027415	Vermium Liquid Each 100ml contains:- Leamisole HCL…….1.5gm	100ml 1 Litre	**12-02-2002** Transfer from Epla Laboratories (Pvt) Ltd., Karachi to M/s. Spencer Pharma (Pvt) Ltd., Karachi on **18-09-2006** **24-08-2016**
8.	022773	Oxole Suspension Contains:- Oxfendazole B.P……2.265% w/v	100ml 450ml 1000ml	**14-04-1999** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on

				18-08-2004 and again transfer to M/s. Spencer Pharma (Pvt) Ltd., Karachi on **18-09-2006** **02-09-2019**
9.	025370	Oxole Gold Suspension Contains:- Oxfendazole B.P……...2.265% w/v Selenium (as Sodium Selenate) USP…….0.05% w/v Cobalt (as Cobalt Sulphate) USP……...0.167% w/v	100ml 450ml 1000ml	**22-05-2000** Transfer from M/s. Barrett Hodgson Pakistan (Pvt) Ltd., Karachi to M/s. Epla Laboratories (Pvt) Ltd., Karachi on 18-08-2004 and again transfer to M/s. Spencer Pharma (Pvt) Ltd., Karachi on **18-09-2006** **24-08-2016**

M/s. Regent Laboratories, Karachihas deposited the required fee Rs. 20,000 x 9 = Rs.180,000/- and submitted following supporting documents:-

(i) Original NOC fromboth firms **M/s. Epla Laboratories (Pvt) Ltd., Karachi**&**M/s. Spencer Pharma (Pvt) Ltd., Karachi** without date.
(ii) Copies of initial registration letter/variation.
(iii) Copy of renewal status.
(iv) Copy of Drug Manufacturing License.
(v) Copy approved sections Powder Veterinary Vitamin (G), Dry Powder for Oral and Oral Liquid.
(vi) GMP inspection report conducted on 09th October, 2019. The panel recommended the DML No.000506 (Formulation) for the following veterinary sections and 5th November, 2019.
(vii) Applications on Form 5.
(viii) Undertaking.

The product at Sr. No. 6 containing**"Furaltadone".**

Decision:- Registration Board decided to defer for NOC confirmation from the manufacturer.

Case.No.04:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 293rd meeting approved following veterinary drug as per decision mentioned alongside each. However, processing of this product for issuance of registration letter was withheld. After receiving registration dossier from PEC applied by M/s. Grand Pharma, Rawat-Islamabad them but mistakenly in minutes the product got approved in favour of "M/s. Evergreen Pharmaceuticals, Lahore" of product "Alben Par 200 Bolus.

1.	M/s. Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th Km Ferozepur Road, Lahore.	Alben Par 200 Bolus Each bolus contains:- Albendazole……200mg	4 x 5's 10 x 5's 20 x 5's	Approved with innovator's specification.

Registration letter has been issued to M/s. Grand Pharma, Rawat-Islamabad after confirmation of dossier received from PEC.

Decision: Registration Board noted and endorsed issuance of registration in favor of M/s. Grand Pharma, Rawat, Islamabad.

Case.No. 05:- Request of M/s. D-Maarson Pharmaceuticals, Rawat, Islamabad registration of drugs.

M/s. D-Maarson Pharmaceuticals, Islamabad has requested for registration of following veterinary products for local manufacture in their name and cancellation of same from the name of M/s. Breeze Pharma (Pvt) Ltd., Islamabad.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Sizes	Remarks
1.	075653	Oxytron LA Injection Each ml contains:- Oxytertracycline ….200mg	50ml 100ml	*04-05-2013* ***20-07-2019*** *Firm requested for grant of 50ml pack.*
2.	059156	Diaminac Granules for Injection Each sachet contains:- Diminazine Diaceturate…..2.36gm	2.36gm sachet	*Sachet manufacturing facility needs to be confirmed.*

M/s. D-Maarson Pharmaceuticals, Islamabad has deposited the required fee Rs. 20,000 x 2 = 40,000 and submitted following supporting documents:-

(i) Original NOC from M/s. Breeze Pharma (Pvt) Ltd., Islamabad.
(ii) Copy of initial registration letters alongwith renewal status.
(iii) Copy of Drug Manufacturing License.
(iv) Undertaking.
(v) GMP inspection report conducted on 06-02-2019
(vi) Applications on Form 5.

Registration Board in its 292nd meeting decided as follow;

S. No.	Reg. No.	Name of Drug(s)/ Composition	Decision
1.	075653	Oxytron LA Injection Each ml contains:- Oxytertracycline ……...200mg	Registration Board deferred the case for confirmation of renewal status of the product.
2.	059156	Diaminac Granules for Injection Each sachet contains:- Diminazine Diaceturate ..2.36gm	Registration Board deferthe case for confirmation of sachet manufacturing facility of the firm.

The firm has provided renewal status for product at Sr. No.1 with double fee submitted within sixty days and sachet manufacturing facility for product mentioned at Sr. No.2.

Decision:- Registration Board decided as follow;

a. **Approved the cancellation of registration of above mentioned products (of above table) from the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.**
b. **Approved the registration of above mentioned products (of above table) in the name of M/s. D-Maarson Pharmaceuticals, Islamabad.**
c. **For product at Sr. No. 1 registration letter will be issued after the confirmation/approval of renewal.**

Case No. 06:- Request of M/s. Ghazi Brothers, Karachi for Change of Name of Manufacturer/ Manufacturer Site for their registered products.

M/s. Ghazi Brothers, Karachi has applied for change of name of manufacturer/manufacturing site for their already registered products as per details mentioned alongside each:-

S. No	Reg. No.	Name of Drug(s)/Composition as per Registration letter	Name of Drug(s)/Composition as per new CoPP	Existing Name of Manufacturer/ Initial date of Registration/ Variation	Request for Change of Name of Manufacturer	Request for Change of Manufacturing Site
(I)	(II)	(III)	(IV)	(V)	(VII)	(VIII)
1.	029685	Lincocin 40% Soluble Powder Each gm contains:- Lincomycin Hydrochloride (corresponding to Lincomycin …400mg)	Lincocin 40% Soluble Powder Each gm contains:- Lincomycin base as LincomycnHydochloride …..0.4000 gram activity Colloidal Silicon Dioixde…….0.0012 gram Lactose Monohydrate…..qs to 1 gram	M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China.	M/s. Zoetis Suzhou Manufacturing Co., Ltd, No.180, Zhu Yuan Road, Suzhou New District, Jiangsu Province, P.R. China.	M/s. Zoetis Suzhou Manufacturing Co., Ltd, 690, Jian Lin Road, Suzhou New District Jiangsu Province, P.R. China.
2.	009990	Lincomix Premix Powder Each Kg contains:- Lincomycin Hydrochloride…110gm	Lincomix 110 Premix Each Kg contains:- Lincomycin base as LincomycinHydrochloride..0.11 gram activity Light Liquid Paraffin…0.01 gram Rice Husk…….qs to 1 gram	-do-	-do-	-do-

3.	017935	Lincomix 44 Premix Powder Each Kg contains:- LincomycinHCl…44gm	Lincomix 44 Premix Powder Lincomycin base as Lincomycin Hydrochloride…0.044 gram activity	-do-	-do-	-do-
4.	009991	Linco-Spectin Powder Containing:- LincomycinHcl 42.19gm (equivalent to Lincomycin base 33.3gm) SpectinomycinSulphate 103.71gm (equivalent to Spectinomycin base 66.7gm)	Linco-Spectin 100 Soluble Powder Contains:- Lincomycin base as Lincomycin Hydrochloride…0.222 gram activity Spectinomycin base as Spectinomycin Sulfate…0.445 gram activity. Sodium Benzoate……0.0107 gam Lactose Monohydrate…..qs to 1 gram	-do-	-do-	-do-

With reference to the instant case it is Animal Health Products Co. Ltd., China" to "M/s. Zoetis Suzhou Manufacturing Co., China" with submitted that the firm initially requested in 2015 for change of name of manufacturer from "M/s. Pfizer Suzhou full fee i.e. Rs.100,000/-for each product. For products 1-3 firm provided attested fee copy (from Allied Bank, Karachi Branch) for product at Sr.No. 4 original fee challan is available. Later, the firm also requested for change of manufacturing site for the said products from "M/s. Pfizer Suzhou Animal Health Products Co., Ltd, China" to "M/s. Zoetis Suzhou Manufacturing Co., Ltd, 690, Jian Lin Road, Suzhou New District Jiangsu Province, P.R. China".

Original request submitted by the firm is being traced, and fee challan alongwith undertaking and provided the following supporting documents. The renewal section has confirmed the renewal of above mentioned drugs. Furthermore, the firm has informed regarding change of brand in remarks column -IV as submitted free sale certificates.

a) Copies of initial Registration letters along with renewal status and post registration variations.
b) Original legalized and attested free sale certificate (issued by Chines Authority.
c) GMP certificate duly legalized by Consulate General of Pakistan for new manufacturing site.
d) Copy of Drug Sale License.
e) Site master file Suzhou.

Registration Board in its 295th meeting deferred for incorporation of complete background of the case. The complete date of initial registration letters/ variation has been mentioned in remarks column-V.

(A) LINCOCIN 40% SOLUBLE POWDER (REGN.NO. 029685)

Registration Date: 05 September 2003(Manufactured by M/s. Pharmacia Animal Health Limited. England,
Variation Approved: 07 April 2004 (Change of local agent from M/s. Pharmacia Pakistan (Pvt.) Ltd., Islamabad to Ghazi Brothers, .
Variation Approved: 07 December 2007 Variation Approved: 07-Dec-2007 (Change of manufacturing site/source, from M/s. Pharmacia Animal Health Ltd., U.K to M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China, corrigendum to approval issued 17-Dec-2007,
Variation Application Submission: 30 July 2015 (Change of name of manufacturer from Pfizer Suzhou Animal Health Products Co. Ltd., China to Zoetis Suzhou Manufacturing Co., Ltd., China,.

Addition to Submitted Variation Application: 05-Oct-2017 (Change of manufacturing site from Zoetis Suzhou Manufacturing Co. Ltd. No. 180 Zhu Yuan Road, Suzhou New District, Jiangsu, China 215011 to Zoetis Suzhou Manufacturing Co. Ltd. No. 690, Jian Lin Road, Suzhou New District Jiangsu, China 215151.

(B) LINCOMIX PREMIX POWDER (REGN.NO. 009990)

Initial Registration: 17-Oct-1988 (Manufactured by M/s. Upjohn S.A., Belgium)

Variation Approved: 07-Apr-2004 (Change of local agent from M/s. Pharmacia Pakistan (Pvt) to M/s. Ghazi Brothers,

Variation Approved: 07-Dec-2007 (Change of manufacturing site/source from M/s Pharmacia Animal Health Ltd., U.K to M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China, corrigendum to approval issued 17-Dec-2007,

Variation Application Submission: 30-July-2015 (Change of name of manufacturer from M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China to Zoetis Suzhou Manufacturing Co. Ltd., China approval awaited,

Addition to Submitted Variation Application: 05-Oct-2017 (Change of manufacturing site from Zoetis Suzhou Manufacturing Co. Ltd. No. 180 Zhu Yuan Road, Suzhou New District, Jiangsu, China 215011 to Zoetis Suzhou Manufacturing Co. Ltd. No. 690, Jian Lin Road, Suzhou New District Jiangsu, China 215151.

(C) LINCOMIX 44 PREMIX POWDER (REGN.NO. 017935)

Initial Registration: 17-Jul-1995 (Manufactured by M/s. Cheminex Laboratories Ltd., U.K,

Variation Approved: 07-Apr-2004 (Change of local agent from M/s. Pharmacia Pakistan (Pvt) Ltd, Islamabad to M/s. Ghazi Brothers,

Variation Approved: 07-Dec-2007 (Change of manufacturing site/source from M/s.Pharmacia Animal Health Products Co., Ltd., UK to M/s Pfizer Suzhou Animal Health Products Co. Ltd., China, corrigendum to approval issued 17-Dec-2007, copies enclosed)

Variation Application Submission: 30-July-2015 (Change of name of manufacturer from Pfizer Suzhou Animal Health Products Co. Ltd., China to Zoetis Suzhou Manufacturing Co. Ltd., China, approval awaited, copy enclosed,)

Addition to submitted variation application:

28-Sep-2016 (Change of name of product from Lincomix 44 Premix Powder to Lincomix 44 Premix). 05-Oct-2017 (Change of manufacturing site from Zoetis Suzhou Manufacturing Co. Ltd., No. 180 Zhu Yuan Road, Suzhou New District, Jiangsu, China 215011 to Zoetis Suzhou Manufacturing Co. Ltd., No. 690, Jian Lin Road, Suzhou New District, Jiangsu, China 215151,

(D) LINCO-SPECTIN POWDER (REGN.NO. 009991)

Variation Approved: 07-Apr-2004 (Change of local agent to Ghazi Brothers,

Variation Approved: 07-Dec-2007 (Change of manufacturing site/source from M/s Pharmacia Animal Health Ltd., U.K to M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China, corrigendum to approval issued 17-Dec-2007,

Variation Application: 04-Feb-2019 (Change of manufacturing site and Brand name correction from **Linco-Spectin Powder** to**Linco-Spectin 100 Soluble powder**,).

Decision: Keeping in view the, Registration Board approved the manufacturer/manufacturing site change in address of importer of above mentioned products from M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China to M/s. Zoetis Suzhou Manufacturing Co., Ltd, 690, Jian Lin Road, Suzhou New District Jiangsu Province, P.R. China subject to inspection of manufacturer abroad as per import policy.

Case No.07:- Cancellation of Drug Manufacturing Licenses by Central Licensing Board.

Central Licensing Board in its 271st meeting held on 12th September 2019 cancelled the Drug Manufacturing License (DML 0003530 (Formulation) of M/s. Kakasian Pharmaceuticals (Pvt) Ltd., 29-Km, Ferozpur Road, Lahore.

The case is submitted for consideration of Registration Board with regard to status of drugs registered with this firm after cancellation of their Drug Manufacturing License.

Registration Board in its 295th meeting defer the case for seeking status from Legal Division whether the firm has challenged decision of CLB or otherwise.

Response of Legal Division as under:

"As per available record, M/s. Kakasian Pharmaceuticals (Pvt) Ltd., 29-Km, Ferozpur Road, Lahore has not filed any appeal in the Appellate \board so far, Moreover, no notice for filling of writ petition has been received in the Division so far"

Decision:- Registration Board decided to cancel the all the registered drugs in the name of M/s. Kakasian Pharmaceuticals (Pvt) Ltd., 29 Km, Ferozpur Road, Lahore.

Case No.08:- Request of M/s. ICI Pakistan Ltd., Karachi for Transfer of Registration from Import to Local Already Registered Veterinary Drugs.

M/s. ICI Pakistan Ltd., Karachi have requested for transfer of registration of following registered imported veterinary drugs import from M/s. Norbrooke Laboratories Limited, Northeren Ireland to local manufacturing at their licensed facility located at M/s. ICI Pakistan Limited, Life Sciences, 45-Km Off. Multan Road, Lahore:-

S. No.	Regn.No.	Name of Drug(s)/Composition	Pack Size(s)	Date of Initial Registration Letter/ Renewal Status
1.	023477	Endectin Injection Each ml contains:- Ivermectin…….10mg	50ml	29-06-1999 29-05-2019
2.	023477	Endectin Injection Each ml contains:- Ivermectin…….10mg	100ml	
3.	048151	Multivor Injection Each ml contains:- Vitamin a (Palmitate)……..15,000 I.U Vitamin D3 (Cholecalciferol) ……..25mcg	100ml	29-02-2016

		Vitamin E (Alpha Tocopheryl Acetate)…… 20mg Vitamin B1 (Thiamine Hydrochloride)……...…10mg Vitamin B2 (Riboflavine Sodium Phosphate)…… ……..5mg Vitamin B6 (Pyridoxine Hydrochloride) ……...…3mg Nicotinamide…….…..... 35mg Dexpanthenol ……..…..25mg Vitamin B12 (Cyanocobalamin)……..25mcg		

M/s. ICI Pakistan Ltd., KarachiLahore has deposited required fee Rs.20,000 x 3 = Rs.60,000/- and submitted following supporting documents:-

(i) Copies of registration letters and renewal status.
(ii) Copy of Drug Manufacturing License alongwith renewal deposited fee submitting in Licensing Division.
(iii) Copy of CRF.
(iv) Copies of Form-5
(v) cGMP inspection report conducted by Federal Inspector of Drugs, Lahore on 25-01-2018.
(vi) Copy of approval liquid injectable (SVP) Vet.
(vii) Undertaking.

Decision:- Registration Board decided to defer for NOC from Product License Holder Abroad.

Case.No.09:- Request of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad Registration of Drugs.

M/s. Breeze Pharma (Pvt.) Ltd., Islamabad has requested for registration of following veterinary products for local manufacture in their name and cancellation of same from the name of M/s. Redex Pharmaceutical Industries (Private) Limited, Karachi.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Sizes	Initial Date of Registration/ Remarks
1.	025349	Devermazole-CS Oral Solution Each ml contains:- Albendazole B.P……...…100mg Cobalt Sulphate B.P……0.382% Selenium Sulphide B.P……0.150%	100ml 500ml 1000ml	09-05-2000
2.	025350	Bovicin-20 Oral Solution Each ml contains:- Enrofloxacin Hcl…….200mg	100ml 500ml 1000ml	09-05-2000

M/s. Breeze Pharma (Pvt.) Ltd., Islamabad has deposited the required fee Rs. 20,000 x 2 = 40,000 and submitted following supporting documents:-

(i) Original NOC **dated 05-09-2018** from M/s. Redex Pharmaceutical Industries (Private) Limited, Karachi.
(ii) Copy of initial registration letter along with renewal status.

(iii) Copy of Drug Manufacturing License.
(iv) Undertaking.
(v) GMP inspection report conducted on 03-08-2017.
(vi) Applications on Form 5.

Registration Board in its 295th meeting defer the case for provision fresh NOC as existing NOC is more than 2 years old.Letter issued to the firm to provide fresh NOC. In response the firm has provided fresh NOC from existing manufacturer dated 17-08-2020.

Decision:- Registration Board decided as follow;

a. **Approved the cancellation of registration of above mentioned products (of above table) from the name of M/s. Redex Pharmaceutical Industries (Private) Limited, Karachi.**

b. **Approved the registration of above mentioned product (of above table) in the name of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad.**

Case.No.10:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 289th meeting held on 14–16th May, 2019 deferred the following drug of M/s. Medi-Vet (Pvt) Limited, Lahore for confirmation of me-too status.

S. #	Name of Drug(s)/Composition	Demanded Composition of the firm.	Pack Size	Shelf Life
(i)	(ii)	(iii)	(iv)	(v)
1.	Floxivet-C Injection Each ml contains:- Enrofloxacin B.P Vet……..……..100mg/ml ColistinSulphate BP…….250000 iu/ml	Floxivet-C Injection Each 100ml contains:- Enrofloxacin BP Vet…10gm Colistin Sulphate BP……....50,000,000IU	100ml 250ml 500ml 1000ml	02 years

The firm has deposited the fee of Rs.20,000/-. As per available record the above mentioned product is not registered in same composition. The firm has requested to change the composition me-too already registered product in various firms including M/s. Zakfas Pharmaceuticals (Pvt) Ltd. Multan ***"Encoras Injection Regn.No.057067"***.

Registration Board in its 295th meeting advised to get justification for reason for change of composition and its approval status accordingly.

Letter issued to M/s. Medi-Vet (Pvt) Limited, Lahore to get justification for reason for change of composition and its approval status accordingly.

Firm reply as under:

Justification for reason for change of composition is our competitor M/s. Zakfas Pharmaceuticals (Pvt) Ltd. Multan having the same composition for me-too with products Encoras Injection Regn.No.057067. The firm has requested to please consider their justification for the registration of their product Floxivet-C Injection.

Decision:- Registration Board deferred for confirmation of generic status from record.

Case No. 11:- Registration of Veterinary Drug under Drug Act, 1976.

Registration Board in its 237th meeting approved following product of M/s. Ghazi Brothers, Karachi for import from M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China subject to inspection of manufacturer abroad as per import policy and verification of storage facility (where applicable) as per detailed mentioned against each:-

S. No.	Name of Importer/ Manufacturer	Name of Drugs/ Composition & Meeting	Decontrolled/ Packs Size	Shelf Life	Decision/ Remarks
1.	M/s. Ghazi Brothers, Karachi. / M/s. HebeiYuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Sinomox LA Suspension for Injection Each ml contains:- Amoxicillin….150mg (15%)	10ml 50ml 100ml 250ml	2 years	Approved

While processing for issuance of registration letter it was observed that the said product is already registered in the name of M/s. Genome Pharma, Islamabad with brand name **"**Amoxygen LA Injection" (Reg.No. 057143) from the same manufacturer/product license holder. M/s. Ghazi Brothers was informed accordingly about the status of the case.

Now, M/s. Ghazi Brothers, Karachi has provided legalized and attested termination letter in favor of "*M/s. Genome Pharma, Islamabad-Pakistan*" from the manufacturer/principal M/s. HebeiYuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province, China.

It is pertinent to mention that inspection of above mentioned manufacturer has already been carried out by nominated panel on 04th and 05th April, 2017 and rated the manufacturing facility as "Good".

The case was discussed in 291st meeting of Registration Board meeting, keeping in view the termination of distribution agreement of M/s. Genome Pharma, Islamabad for product "Amoxygen LA Injection" (Reg.No. 057143) by M/s. HebeiYuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province-China, Registration Board decided to issue show cause notice to M/s. Genome Pharma, Islamabad as to why the registration of aforesaid product may not be cancelled because of termination of distribution agreement.

Accordingly show cause notice issued on 30thDecember, 2019 and reminder issued on11th February, 2019 to M/s. Genome Pharma, Islamabad. But reply is still awaited.

Registration Board in its 295th meeting decided to issue final reminder toM/s. Genome Pharma, Islamabad. A copy of same will also be sent to concerned DRAP office for handing over to the firm.

Accordingly final reminder issued to M/s. Genome Pharma, Islamabad to submit your reply within five days, failing to which it will be presumed that you have nothing to offer in your defense and ex-parte decision would be taken in Registration Board, but **reply is still awaited**.

Decision:- Registration Board decided to issue final show cause notice toM/s. Genome Pharma, Islamabad to submit reply within 15 days.

Case No. 12:- Cancellation of distribution agreement of M/s. SS Associates, Lahore by their principal abroad (Turkey).

M/s. Medicavet, Turkey informed vide letter about termination of distribution agreement with M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahore ***w.e.f. 18-01-2019*** and further informed about appointment of *M/s. Unicare Enterprises, Faisalabad* (Head Office: M/s. Unicare Enterprises, Commercial -06, 1st Floor, Block-A, Kazimabad, Model Colony, Karachi, Pakistan-75100) (Regd. Office: Reg. Office: Plot No. 587/1-B, Street No.3, Punjab Small Industrial Estate, NalkaKohala, Sargodha Road, Faisalabad) as their new distributor. M/s. Medicavet, Turkey also provided a copy of termination notice addressed to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahore.

Details of registration applications submitted by M/s. SS Associates, Lahore from the above mentioned principal is as follow:-

S.No	Name of Drugs/Composition / Meeting No.	Name of Manufacturer	Remarks
1.	Mediquinol 10% Oral Liquid Each ml contains:- Enrofloxacin…...100mg **(M-277)**	M/s. Medicavet, TarimHayvancilikIlacveKimya San. Tic. Ltd. Sti. ItosbEski Ankara AsfaltiUzeri 12. Cadde No: 1 34959 Tepeoren Tuzla Istanbul, Turkey.	Inspection of the manufacturer abroad has been carried by the nominated panel on 27th& 28th September, 2018 and recommended the facility.
2.	Medicol 24% Oral liquid Each ml contains:- Colistin Sulfate……..240mg **(M-277)**	-do-	-do-
3.	Nemason Water Soluble Powder Each gram contains:- LevamisoleHydrochloride…150mg **(M-277)**	-do-	-do-
4.	Synercid Water Soluble Powder Each gm contains:- Amoxicillin	-do-	Panel for inspection of Penicillin Section of manufacturer has been constituted comprised of Mr.

	(as Trihydrate)…720mg Colistin Sulphate…….180mg **(M-284)**		Abdullah and Mr. AjmalSohailAsif.

Keeping in view the termination of distribution agreement of M/s. SS Associates, Lahore by M/s. Medicavet, Turkey, Registration Board decided to issue show cause notice to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahoreas to why the approval for registration of veterinary products may not be cancelled because of termination of their distribution agreement.

Accordingly show cause notice issued to M/s. SS Associates, Lahore on 30th December, 2019 and letter is undelivered and again letter to the firm another company address but letter is again undelivered.

Registration Board in its 295th meeting decided to issue final reminder to M/s. SS Associates, Lahore. A copy of same will also be sent to concerned DRAP office for handing over to the firm.

Accordingly final reminder issued to M/s. SS Associates, Lahore to submit your reply within five days, failing to which it will be presumed that you have nothing to offer in your defense and ex-parte decision would be taken in Registration Board, but letter is undelivered.

Decision:- Registration Board decided to issue final show cause notice to M/s. SS Associates, Lahore to submit reply within 15 days. DRAP Lahore will be advised to

Case.No.13:- Registration of Drugs.

Registration Board in its 289th meeting approved following veterinary drugs in the name of M/s. Chakwal Pharma International, Lahore for import from M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands. Details are as follow;

S. No.	Approved Products of M/s. ChakwalPharma, Lahore/ Manufacturer	Details of Already Registered Products.	Regn. No.
	II	III	IV
1.	Alfamec1% Solution for injection Each ml contains:- Ivermectin…….10mg Manufactured By M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Alfamec 1% Injectable Solution. Each ml contains:- Ivermectin…….10mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured By M/s. Alfasan International B.V., The Netherlands.	048180
2.	Lincomycin-Spectinomycin 5/10 Solution for injection Each ml solution contains:- Lincomycin (as Hydrochloride)……..50mg Spectinomycin (as Hydrochloride)……..…….100mg	Lincomycin-Spectinomycin 5/10 Injectable Solution. Each ml contains:- Lincomycin (as HCl)……...50mg Spectinomycin (As HCl)...100mg	048182

	Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerdenNetherlands.	M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	
3.	Xylazine 2% Solution for injection Each ml solution contains:- Xylazine (as Hydrochloride)…….20mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Xylazine 2% Injectable Solution. Each ml contains:- Xylazine (as HCl)……20mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048181
4.	Multivitamin Solution for injection Each ml solution contains:- Vitamin A…15,000 IU Cholecalciferol…1000 IU Alfa-Tocoferol Acetate…20mg Thiamine Hydrochloride…10mg Riboflavine Sodium Phosphate…6.85mg Pyridoxine Hydrochloride…3mg Cyanocobalamine….50mcg Nicotinamide….35mg D-Panthenol…..…25mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Multivitamins Injectable Solution. Each ml contains:- Vitamin A (as Synthetic concentrate oily form) ....15000 IU. Cholecalciferol (as concentrate Oily form) ……1000 IU. Alpha Tocopheryl Acetate …..20mg. Thiamine Hydrochloride ……..10mg. Riboflavine Sodium Phosphate....6.85mg. Pyridoxin Hydrochloride…….3mg. Cyanocobalamin…50mcg. Nicotinamide…35mg. Dexpanthenol …25mg. M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048185
5.	Amoxycilline 20% LA Suspension for Injection Each ml Suspension contains:- AmoxycillinTrihydrate……..…200mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	AmoxcinTrihydrate 20% Injectable Each ml contains: - AmoxycillinTrihydrate equivalent to 200mg amoxycillin base M/s. Shayan Traders Rawalpindi./ Manufactured by M/s. AlfasanInt Holland.	022144

While processing of registration letters it has been observed that the same products are already found registered in the name of other importers (M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Traders Rawalpindi). M/s. ChakwalPharma International, Lahore informed that their principle had already cancelled the agency agreement dated 06-03-2009 due to not reaching the agreed annual targets for several years and provided a copy of it.

The case was again discussed in 291st meeting the Registration Board decided to issue show cause to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Trader, Rawalpindi as to why the registration of the abovementioned products may not be cancelled because of termination of their distribution agreement.

Accordingly show cause notices issued to both firms;

M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reply against show cause is as under:

(i) We strongly object to the cancellation of subject registrations since it is violation of their agreement with M/s. Alfasan, Netherlands. We never received notice of termination of ouragreement with M/s. Alfasan, Netherlands and reason behind this invalid termination.Prior to agreement with M/s. Alfasan, Netherlands, the products of this company are being counterfeited in Pakistan by their previous agent M/s. Lexicon Pharma. It was Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi that exposed M/s. Lexicon Pharma and its illegal counterfeit business and underwent extensive legal and operational costs in initiating legal proceedings against M/s. Lexicon Pharma.

(ii) M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachispent hugeamounts of money in getting Alfasan Netherlands out of the grips of counterfeiters M/s. Lexicon Pharma which is included legal costs, market surveys, travelling costs and products registration and transfer costs. Furthermore, Alina Combine pharmaceuticals has over the regularly paid the required DRAP fees to maintain the products registrations valid in Pakistan, hence they are asked to right to market these products in Pakistan given the extensive costs borne by us the effort and hardships faced by us in securing the interest of M/s. Alfasan in Pakistan.

(iii) Considering the above believe that DRAP should secure the interest of its genuine importers/manufacturers who have over the years exposed the counterfeit and spurious manufacturers and helped international manufactures as a result. They gone the extra length and paid exorbitant amounts in legal costs and various other expenses without any compensation to date from M/s. Alfasan Netherlands.

(iv) In lieu of above, we again submit that strongly object to the notion of consideration of cancellation of their registered products and hope that Board will give justified consideration to their case and not cancel our valid registration.

For product at Sr.No.5, show cause notice issued to M/s. Shayan Traders Rawalpindi but letter was undelivered. As per record the product has been transfer from M/s. Shayan Traders Rawalpindi to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi vide letter No.F.2-2/2007-Reg-I (Vet) dated 16th April, 2007.

Registration Board in its 295th meeting defer the case for provision of fresh sole agency agreement / authorization letter from the manufacturer abroad in the name of M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi.

Accordingly letter issued to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi for provision of fresh agreement/authorization letter the manufacturer abroad. **The reply is still awaited**. Meanwhile the manufacturer abroad i.e.M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands submit a letter in the name of Chairman, Registration Board, DRAP, Islamabad which is reproduced as under:

(i) AlfasanInternational has terminated its sole distribution agreement with Alina Combine Pharmaceuticals (Pvt) Ltd. on ground of non-compliance dated 26-01-2010.

(ii) No transaction of any nature took place between Alfasan International and Alina Combine Pharmaceuticals (Pvt) Ltd. after termination of sole distribution.

(iii) This termination of sole distribution rights for Alina Combine Pharmaceuticals (Pvt) Ltd. has been communicated/submitted to DRAP via our letter dated 22-July, 2019 (copy attached for your ready reference).

(iv) The registration applications submitted by Alina Combine Pharmaceuticals (Pvt) Ltd. to transfer registration from import to local manufacturing is without our consent and we do not allow Alina Combine Pharmaceuticals (Pvt) Ltd. to use our brand name of any intellectual property of Alfasan International.

(v) Moreover, Alfasan International has never authorized Alina Combine Pharmaceuticals (Pvt) Ltd. to manufacture/produce/market veterinary medicines using Alfasan International brand name and we strongly oppose them doing so.

(vi) Alfasan International do not intend to provide Alina Combine Pharmaceuticals (Pvt) Ltd. with renewed sole distributorship agreement or any authorization letter whatsoever.

Furthermore, Alfasan International has appointed *M/s. ChakwalPharma International located at OTI Plaza, Basement, Ground, 1st, 2nd& 3rd Floor, 210 Lalazar Commercial Market, ThokarNiazBaig, Raiwind Road, District Lahore* has sole distributor of veterinary medicines since May 5th, 2017, and as such have been authorized to officially follow up registration issues on our products in Pakistan.

It is therefore requested to process registration of products in name of *M/s. ChakwalPharma International*as approved by Honorable DRAP Registration Board in 289th meeting of Registration Board (14-16 May, 2019) and oblige.

Decision:- Registration Board decided to issue final show cause notice to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi to submit reply within 15 days.

Case No. 14:- Request of M/s. Leads Pharma (Pvt) Ltd., Islamabad for Additional Pack Size for already Registered Veterinary Drug.

M/s. Leads Pharma (Pvt) Ltd., Islamabad has applied for approval of additional pack of their registered veterinary drugs as per details mentioned below:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already granted Pack Size	Demanded Additional Pack	Remarks/ Diary No./ Justification
1.	079124	Broxy Oral Solution Each 1000ml contains:- Tylosin Tartrate……..100gm Doxycycline HCL……...200gm ColistinSulphate……..450MIU Bromohexine……...4gm	100ml 200ml 250ml 500ml 1Litre	5 Litre	Dy. No. 21677 (R&I) DRAP dated 27-08-2020 Due to demanded by the veterinary prescribes and marketing due to being economical for the farmer to purchase.

M/s. Leads Pharma (Pvt) Ltd., Islamabadhas deposited the required fee of Rs.5,000/- and submitted following supporting documents:-

(i) Copy of initial registration letter.
(ii) Copy of renewal status.

(iii) Latest GMP inspection report conducted on 29-11-2018 & 01-01-2019.
(iv) Copy of Drug Manufacturing License.
(v) Undertaking.

The demanded pack size is not given to other firms.

Decision:- Keeping in view justification given by the applicant, Registration Board approved M/s. Leads Pharma (Pvt) Ltd., Islamabad request for grant of additional pack size of "5 Litre" to their registered veterinary product Broxy Oral Solution (Reg.No. 079124) on same terms and conditions.

Case No. 15:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 287th meeting approved following veterinary drugs in the name M/s. International Pharma Labs., Lahore. However, further processing of these products for issuance of registration letters were withheld to confirm the intra-mammary injection manufacturing facility from Licensing Division.

The Licensing Division has submitted that as per available record of Licensing Division, pre-filled injection facility has not been granted to M/s. International Pharma Labs., Lahore under DML No.000582 (Formulation).

The details are as under:-

S. No.	Name of Manufacturer	Name of drug(s) & Composition	Approved Packs Size	Decision & Remarks
1.	M/s. International Pharma Labs. Raiwind Road, BhobtianChowk, defence Road, 1-KM Towards Kahna, Lahore.	Cephra Injectable Solution Each 4gm contains:- Cephradine……..300mg Neomycin Sulphate….200mg Prednisolone Sulphate….5gm	4gm Syringe	Approved with Innovator's specifications.
2.	-do-	I-Multivet IMM Injection Each 5gm contains:- Procaine Penicillin…..100,000IU StreptomyinSulphate…..100mg NeomyinSulphate……100mg Prednisolone……...10mg	5gm	Approved with Innovator's specifications.
3.	-do-	Linconepre Injection Each injection contains:- Lincomycin as HCl……..200mg Neomycin as Sulphate….200mg Prednisolone……5mg	5gm	Approved with Innovator's specifications.

Decision:- Registration Board deferred for further deliberation regarding manufacturing requirements of these products.

HUMAN IMPORT

Case No.01 **REQUEST OF M/S ZAM ZAM CORPORATION, KARACHI FOR EXEMPTION OF URDU LABELING, MRP & IMPORT OF STANDARD PACKING FOR FINISHED IMPORTED PRODUCTS FUCIDIN TABLET (REG. NO.005964) & DAIVOBET OINTMENT (REG.NO.031379)**

M/s Zam Zam Corporation, Karachi has stated that their foreign manufacturer produces bulk to cater the need of more than 50 countries this becomes difficult for the manufacturer to make specialized pack for Pakistan only as quantity of import is small on yearly business hence, principal has informed that in future only international pack would be exported, which will have no Urdu version and Pakistan Registration number.

The firm is requested to allow them to print Urdu labeling, registration no. and MRP on the international pack. on **their license premises (DSL)** before sale / market. Detail of products as under:

S. No.	Product(s) Description	Reg.No.	Pack Size
1.	Fucidin Tablets	005964	20's
2.	Daivobet ointment	031379	15gm

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.5000/- for each product.
b. Copy of registration letter with post registration variation trial.
c. Copy of valid Drug Sale License.

Decision: **Registration Board deferred the case and advised the firm to submit reasons for exemption in subject case along with contract with Drug Manufacturing License (DML) Holder for printing of Urdu Labeling, Registration No. & MRP.**

Case. No.02:- **REQUEST OF M/S LUNDBECK PAKISTAN (PRIVATE) LIMITED, KARACHI FOR CHANGE OF GODOWN ADDRESS (LOCAL) FOR THEIR REGISTERED PRODUCTS.**

The firm has requested for change of their office and store address. Details are as under:-

S. No.	Name of Document	Details as per old DSL (Lic. No.0461)	Details as per New DSL (Lic. No.0985) valid 18-06-2021
1.	**Proprietor Name**	Muhammad Aslam Shaikh S/o Ghulam Rasool	No change
2.	**Head Office address**	40 T/4 Blessing Street Block-6, PECHS, Karachi	No change
3.	**Godown Address**	F-24, SITE, Karachi	Plot No. Z-2-A, SITE, Manghopir Road, Karachi

Details of registered products as per approval		
S. No.	**Reg. No.**	**Name of Product**
1.	005327	Fluanxol Depot Injection 40mg/2ml Each 2ml contains: - Flupenthixol……40mg
2.	005517	Clopixol Deport Injection 200mg/1ml 200mg Zunclopenthixol decanoate Ph.Eur. In 1ml thin vegetable oil sterile
3.	018969	Clopixol Tablets 25mg Each tablet contains:

		Zuclepentixolum…..25mg
4.	008023	Clopixol Acuphase Injection 100mg/2ml Zunclopenthixol acetate 100mg in 2ml thin vegetable oil
5.	028467	Cipralex 10mg Tablets Each tablet contains:- Escitalopram oxalate…….. 12.77mg Escitalopram…….10mg
6.	059035	Cipralex Film Coated Tablets 20mg Each tablets contains: - Escitalopram as oxalate USP…20mg
7.	016323	Cipram Tablets 20mg Each tablet contains: - Citalopram 20mg as hydrobromide
8.	031396	Ebixa 10mg Tablets Each tablet contains: - Memantine Hydrochloride 10mg (equivalent to 8.31mg Memantine)
9.	066178	Ebixa 20mg Tablets Each tablet contains: - Memantine HCL 20mg.

The firm has submitted the following supporting documents: -

a. A Total fee of Rs.45,000/- (9 x 5000=45000)
b. Copy of new Drug Sale License (validity.18-06-2021).
c. Copy of previous Drug Sale License.
d. Complete post registration variation trail and renewal trail (Renewal are valid for all products as per submitted record)

Decision: Keeping in view the new Drug Sale License; Registration Board approved the change of godown address of importer as per following detail:

S. No.	Name of Document	Details as per old DSL (Lic. No.0461)	Details as per New DSL (Lic. No.0985) valid 18-06-2021
1.	**Proprietor Name**	Muhammad Aslam Shaikh S/o Ghulam Rasool	No change
2.	**Head Office address**	40 T/4 Blessing Street Block-6, PECHS, Karachi	No change
3.	**Godown Address**	F-24, SITE, Karachi	Plot No. Z-2-A, SITE, Manghopir Road, Karachi

Case No. 3 <u>REQUEST OF M/S HOSPITAL SUPPLY CORPORATION, KARACHI FOR CHANGE OF ADDRESS OF MANUFACTURING SITE (MEDICAINE INJECTION REG. NO.023645)</u>

M/s Hospital Supply Corporation, Karachi has applied for approval of change of address of manufacturing site for their already registered product medicaine injection (Reg. No. 023645) as per details given below:

Reg. No.	Name & Composition (as per approval)	Existing approved Manufacturing Site (as per approval)	New Proposed Site / Manufacturer & Product License Holder (as per COPP)
023645	**As per Approval** Kwang Myung Lidocaine HCL Injection. Each 1.8ml cartridge contains:- Lidocaine Hcl USP 36mg.	M/s Kwang Myung Pharm. Co. Ltd 907, Sangshin – RI, Hyangnam – Myun, Hwaseong-Kun, KyuncGI-Do, Rep. of Korea.	**Manufacturer & Product License Holder: -** M/s Huons Co., Ltd, 100 Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

	Epinephrine Bitrtrate USP 0.324mg (Eq to 0.018mg of Epinephrine) **As per Transfer letter** Kwang Myung Lidocaine HCL Injection (Medicaine Injection)		

The firm has submitted the following supporting documents: -

1. Fee of Rs. 100,000/- dated 09-07-2019.
2. Application on Form-5F
3. Copy of initial registration letter 26-05-1999 & transfer letter 15-05-2000 with renewal last renewal status.
4. Original & legalized COPP with free sale status of the product.
5. Original & legalized GMP certificate
6. Original & legalized Free Sale Certificate.
7. Original agent agreement
8. Letter of Authorization from product license holder.
9. Copy of DSL.
10. Prescribed undertaking.

Decision: **Registration Board approved the change of address of manufacturing site of following registered product medicaine injection (Reg. No. 023645) subject to policy for inspection of manufacturer abroad for imported finished drugs. Other terms and conditions will remain the same.**

Reg. No.	Name & Composition (as per approval)	Existing approved Manufacturing Site (as per approval)	New approved Site / Manufacturer & Product License Holder (as per COPP)
023645	**As per Approval** Kwang Myung Lidocaine HCL Injection. Each 1.8ml cartridge contains:- Lidocaine Hcl USP 36mg. Epinephrine Bitrtrate USP 0.324mg (Eq to 0.018mg of Epinephrine) **As per Transfer letter** Kwang Myung Lidocaine HCL Injection (Medicaine Injection)	M/s Kwang Myung Pharm. Co. Ltd 907, Sangshin – RI, Hyangnam – Myun, Hwaseong-Kun, KyuncGI-Do, Rep. of Korea.	**Manufacturer & Product License Holder: -** M/s Huons Co., Ltd, 100 Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

Case No. 4. REQUEST OF M/S HOSPITAL SUPPLY CORPORATION, KARACHI FOR INCLUSION OF SHELF LIFE IN THE REGISTRATION LETTER (MEDICAINE INJECTION REG. NO.023645)

M/s Hospital Supply Corporation, Karachi has submitted a request for inclusion of shelf life i.e. 03 years in the already registered drug "Medicaine Injection" (Reg. No.023645**)** as per following details;

Sr. No	Reg. No	Marketing Authorization Holder & Manufacturer (As per Submitted Copp)	Name & Composition (as per approval)	Existing Shelf Life	Proposed Shelf Life
1	023645	**Manufacturer & Product License Holder: -** M/s Huons Co., Ltd, 100 Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea	**As per Approval** Kwang Myung Lidocaine HCL Injection. Each 1..8ml cartridge contains:- Lidocaine Hcl USP 36mg.	Not mentioned in Reg. letter	03 Years

			Epinephrine Bitrtrate USP 0.324mg (Eq to 0.018mg of Epinephrine) **As per Transfer letter** Kwang Myung Lidocaine HCL Injection (Medicaine Injection)		

The firm has submitted the following supporting documents: -

i. Application on form-5F along with fee Rs.5000/-
ii. Copy of initial registration letter 26-05-1999 & transfer letter 15-05-2000 with renewal last renewal status.
iii. Original & legalized COPP with free sale status of the product.
iv. Original & legalized GMP certificate
v. Original & legalized Free Sale Certificate.
vi. Original agent agreement
vii. Letter of Authorization from product license holder.
viii. Copy of DSL.
ix. Prescribed undertaking.

Decision: Registration Board considered request of firm and approved shelf life of 03 years for already registered drug "Medicaine Injection" (Reg. No.023645)

Case. No.5 <u>REQUEST FOR CHANGE IN NAME OF IMPORTER WITH NO CHANGE OF PROPRIETOR.</u>

M/s Fresenius Kabi Pakistan (Pvt) Ltd, Lahore has requested for change of company name from M/s Fresenius Kabi Pakistan to M/s Fresenius Kabi Pakistan (Pvt) Ltd. The details are as under:-

Details of firm

Current Name of Firm	**Proposed Name of Firm**
M/s Fresenius Kabi Pakistan.	M/s Fresenius Kabi Pakistan **(Pvt)** Ltd.
Premises address on old DSL	**Premises address on New DSL**
1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27 C/3, Gulberg-III, Lahore**.**	No change
Godown address on old DSL	**Godown address on New DSL**
M/s. Agility-Logistics (Pvt) Ltd. RLC-2, 26 KM, Multan Road, Opposite Hussaini Darbar, Near Shamshad Farm House, Lahore).	No change

Detail of Product

S. No.	**Name of Drug (s), Composition & Reg. No. (as per approval)**	**Remarks**
1.	Ketosteril Tablet Each coated tablet contains: Tyrosine…30mg Histidine…38mg Threonine…53mg Tryptophan…23mg Lysine acetate…105mg Calcium-4-methyl-2-oxo-valerate…101mg Calcium-2-oxo-3-phenyl-propionate…68mg Calcium-3-methyl-2-oxo-butyrate…86mg Calcium-3-methyl-2-oxo- valerate…67mg Calcium-DL-2-hydroxy-4-methylthio- butyrate…59mg Reg. No**.** 095878	Initial registration letter issued on 30-05-2019.
2.	Nephrosteril solution for infusion Each litre contains: - L-Isoleucine…5.10gm	

	L-Leucine…10.30gm L-Lysine Monoacetate…10.01gm eq to L-Lysine..7.1g L-Methionine…2.80gm Acetyl Cysteine...0.50gm eq to L-Cysteine…0.37gm L-Phenylalanine…3.80gm L-Threonine…4.80gm L-Tryptophan…1.90gm L-Valine…6.20gm L-Arginine…4.90gm L-Histidine…4.30gm Aminoacetic acid…3.20gm L-Alanine…6.30gm L-Proline…4.30gm L-Serine…4.50gm L-Malic Acid…1.50gm Acetic acid 99%...1.382gm Reg. No**.** 095879	
3.	Fresofol 1% Emulsion for intravenous injection Each ml emulsion contains: - Propofol……10mg Reg. No**.** 099009	Initial registration letter issued on 22-10-2019.

Requirements (No SOP is Available)	**Firms Response**
a) Application with required fee as per relevant SRO (in case of similarity / resemblance with drug, fee will not be required).	a) A fee of Rs.15000/-
b) Copy of registration letter and last renewal status.	b) Copies of registration letters provided renewal not due.
c) Copy of Drug Sale License with new name.	c) Provided
d) Approval of new name by SECP / registrar of firm.	d) Copy of certificate of incorporation by SECP.
e) Sole Agency agreement with new name of importer by Manufacturer or product License Holder.	e) Copy of letter of authorization from manufacturer.
f) Undertaking by the firm that no case is pending at any forum / court of law regarding previous name. Undertaking that the provided information/ documents are true/ correct.	f) Undertaking provided by the firm.
g) NOC from Previous proprietor (M-284 Decision)	g) No change.

Decision: Registration Board deferred for submission of remaining fee for above products.

Case. No.6 <u>REQUEST FOR CONTINUATION OF BUSINESS WITH IN-HOUSE SPECIFICATION FOR TWO YEARS (FRESOFOL 1% REG. NO. 099009).</u>

M/s Fresenius Kabi Pakistan (Pvt) Ltd, Lahore has requested as under: -

"We applied for the transfer of our product (Fresofol 1%) from Ms. MediPak importer to Ms. Fresenius Kabi Pakistan (Pvt.) Ltd. with in-house specification (validated method) but the registration letter issued with B.P. Specification as per Drug (Specifications) rules, 1978.

The above said product was already marketed in Pakistan with In-House Specification before transfer. As the same product is registered in Reference countries with in-house specification and marketed. We need some time to update our product specification as per Pharmacopeia for Pakistan.

We request to provide two years wavier for us to be compliant with Pharmacopeia Specification and allow us to import with in-house Specification till that time. We assure, we will update and submit the documents upon completion of this process".

Fresofol 1% Comparison of In-House Specifications with BP and USP				
Sr.#	**Specification**	**BP Limits**	**USP Limits**	**In House Limits**
1.	Appearance	Not Present	Not Present	visual (white, homogenous emulsion)
2.	pH	6-8.5	4.5-8.5	7.5-8.5
3.	Density	Not Present	Not present	0.9940 - 0.9960 g/mL
4.	Osmolality	Not Present	Not present	270 - 330 mOsmol/kg
5.	fat droplet distribution ≤ 1.5 µm	Not Present	-	≥95%
6.	fat droplet distribution ≤ 5 µm	Not Present	99.95%	100%
7.	fat droplet size ≤ 300nm	≤2µm	<500nm	mean fat droplet size ≤ 300nm
8.	Peroxide	Not Present	Not present	≤3.0mEqu/L
9.	Extractable volume	Not Present	Not present	Not less than nominal volume
10.	ID: Propofol (IR)	Confirm to reference spectra	Not present	Not present
11.	ID: Propofol (HPLC)	Positive	-	Positive
12.	ID: Propofol (UV)	Not present	-	Positive
13.	ID + assay: Propofol	95%-105%	90%-110%	9.50 - 10.50 g/L (95%-105%)
14.	Assay: Phosphor	Not Present	Not Present	0.45g/L (0.40 - 0.50 g/L)
15.	Impurities: Total	Not Present	Not Present	≤0.5%
16.	Individual Unknown (Largest)	Not Present	Not Present	≤0.1%,
17.	Impurity I (Dimer) 4,4-Bis (2,6-diisopropylphenol)	≤0.25%,	0.5%	≤0.1%,
18.	Impurity II (Quinone)2,6-Diisopropyl-1,4-benzo-quinone	≤0.1%,	0.5%	≤0.1%,
19.	NEFA = FFA Non-esterified fatty acids (NEFA), free fatty acids (FFA)	Titration ≤7mmol/L	Titration ≤7mmol/L	Titration ≤12mmol/L
20.	Lysolecithin	HPLC-UV (250µL injection loop, ≤ 0.2% w/v	Not Present	Not Present
21.	Bacterial endotoxin	< 1.65 IU/mL	< 0.33USP Endotoxin Units/mg	< 0.5 IU/mL
22.	Sterile	Sterile	Sterile	Sterile

Remarks: Firm initially apply for two year wavier , now firm request for manufacturer specification

Firm has submitted a fee of Rs. 5000/-

Decision: Registration Board deferred for justification of non-inclusion of Lysolecithin test in manufacturer specification as it is mandatory as per BP monograph.

Case.No.7:- REQUEST OF M/S UNIVERSAL DENTAL (PVT) LTD, KARACHI FOR CHANGE OF IMPORTER TITLE & ADDRESS (LOCAL) FOR THEIR REGISTERED PRODUCT.

The firm has requested for change of their office and store address. Details are as under:-

S. No.	Name of Document	Details as per old DSL (Lic. No.3423)	Details as per New DSL (Lic. No.05-352-0063-030726D) valid 12-03-2020
	Name of Importer	**M/s Universal Dental Supply Co.**	**M/s Universal Dental (Pvt) Ltd.**
	Proprietor Name	N/A	Mr. Saleem Hayee S/o Abdul Hayee
	Head Office address	N/A	17, Macload Road, District Lahore
	Godown Address	N/A	17, Macload Road, District Lahore

Details of registered products as per approval		
S. No.	**Reg. No.**	**Name of Product**
1.	002277	Lignocaine HCL 2% with Adernaline 0,001%

The firm has submitted the following supporting documents: -

a. A Total fee of Rs.5,000/-
b. Copy of new Drug Sale License (validity. 12-03-2020).
c. Copy of previous Drug Sale License.
d. Complete post registration variation trail and renewal trail (Renewal are valid for all products as per submitted record)

Decision: Registration Board deferred for submission of remaining fee and RRA status for above product.

Case.No.8: REQUEST OF M/S. MEHRAN INTERNATIONAL, KARACHI FOR CHANGE OF MANUFACTURING SITE FOR THEIR REGISTERED PRODUCT.

M/s. Mehran International, 498-C, Feroz Shah Mehra Road, Karachi has applied for change of manufacturing site of their following registered product as per details given below: -

Name / Composition / Reg. No.	Existing Manufacturing Site (as per approval)	Proposed Site / Manufacturer & Marketing Authorization Holder (as per COP)
Paracetamol Infusion 1g/100ml Each vial (100ml) contains:- Paracetamol……....1000mg (As per Innovator's Specification)* Reg. No. 094761	**Manufacturer & Product License Holder.** M/s. Jiangsu Pengyao Pharmaceutical Co., Ltd., No.10, Chaquan Road, Yixing City, Jiangsu, 214205, China	**Name & Address of New Manufacturer & Product License Holder.** M/s Cisen Pharmaceutical Co., Ltd, Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China

The firm has submitted the following supporting documents: -

a) Application on From-5F.
b) Fee of Rs.100,000/- for the product.
c) Original and legalized CoPP of the product.
d) NOC from previous manufacturer.
e) Copy of registration letter (issued on 02-05-2019)

Decision: Registration Board approved the change of Marketing Authorization Holder & Manufacturing site of following product subject to policy for inspection of manufacturer abroad for imported finished drugs. Other terms and conditions will remain the same.

Name / Composition / Reg. No.	Previous Manufacturing Site (as per approval)	New Approved Manufacturer & Marketing Authorization Holder (as per COP)
Paracetamol Infusion 1g/100ml Each vial (100ml) contains:- Paracetamol……...1000mg (As per Innovator's Specification)* Reg. No. 094761	**Manufacturer & Product License Holder.** M/s. Jiangsu Pengyao Pharmaceutical Co., Ltd., No.10, Chaquan Road, Yixing City, Jiangsu, 214205, China	**Name & Address of New Manufacturer & Product License Holder.** M/s Cisen Pharmaceutical Co., Ltd, Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China

Case. No.9 REQUEST FOR CHANGE IN ADDRESS OF M/S ANGELINI PHARMACEUTICALS (PVT) LTD, LAHORE.

The subject case was discussed in 295th meeting of Registration Board as under: -

M/s Angelini Pharmaceuticals (Pvt) Ltd, Lahore has submitted requested for change in address and they have shifted to new premises with no change in proprietor The details of registered drug, company name, Godown address etc as per DSL are as under: -

Details of firm

Current Name of Firm / Proprietor.	Proposed Name of Firm / Proprietor.
M/s Angelini Pharmaceuticals (Pvt) Ltd, Lahore Mr. Raza Masud S/o Masud Akhtar	No change
Previous address as per old DSL	**Proposed address as per New DSL**
221-CCA, Phase 4, DHA, District Lahore	Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore

Details of Product

S. No.	Name of Drug (s), Composition & Reg. No. (as per approval)	S. No.	Name of Drug (s), Composition & Reg. No. (as per approval)
1.	Monurol Sachet, Each 3gm Sachet contains: - Fosfomycin Tromethamel 5.631gm (equivalent to Fosfomycin 3gm) Reg. No. 022663	2.	Brumixol Cream Each 100gm contains: - Ciclopiroxolamine 1gm Reg. No. 043074
3.	Brumixol Ovules Each ovule contains: - Ciclopiroxolamine 0.1gm Reg. No. 043075	4.	Lantigen B Suspension Each ml contains:- Streptococcus penumonial type 63.2 Antigenic units. Streptococcus pyogenes group A 126.2 Antigenic

			units. Branhamella Catarrhalis 39.9 Antigenic units. Staphylococcus aureus 79.6 Antigenic units. Haemonhilus influengae type B 50.2 Antigenic units. Klebsiella pneumonia 39.8 Antigenic units. Reg. No**.** 018229
5.	Fluimucil 200mg Sachets Each 1gm sachet contains:- Acetylcysteine 200mg. Reg. No**.** 021174	6.	Spasmex Injection IM/IV Each 4ml vial contains:- 1,2,3 Trihydroxybenzene dehydrate (phlereglucine dehydrate) 51.43mg. (equal to waterless phleroglucine 40mg) Reg. No**.** 021929
7.	Spasmex Tablet Each 4ml vial contains:- 1,2,3 Trihydroxybenzene dehydrate (phlereglucine dehydrate 102,850 (equal to waterless phleroglucine 80mg) - 1,2,3 Trihydroxybenzene 80mg. Reg. No**.** 021930		

Requirements (No SOP is Available)	**Firms Response**
a) Application with required fee as per relevant SRO (in case of similarity / resemblance with drug, fee will not be required). b) Copy of registration letter and last renewal status. c) Copy of Drug Sale License with new name.	a) A fee of Rs.5000/- for each product. b) Firm has submitted complete post registration variation detail. c) Copy of Old DSL & new DSL.

Decision of 295th meeting: Keeping in view the new Drug Sale License; Registration Board decided as follows:

a) Approved firm's address from M/s Angelini Pharmaceuticals (Pvt) Ltd, 221-CCA, Phase 4, DHA, District Lahore to M/s Angelini Pharmaceuticals (Pvt) Ltd, Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore for products at S.No.1, 5,6 and 7. Inspection of storage facility will be conducted for new address/ site before processing of letter.
b) Deferred products at SNo.2 and 3 for confirmation of renewal status
c) Referred product at SNo.04 to Biological Division being biological product.

Fresh Proceedings:-

The firm has deposited requisite additional fee Rs.40,000/- vide slip No. 1939617 & 1939614 dated 13th August, 2020 for the products mentioned at Sr. No. 2 & 3 in decision point "b" .

Following products of the firm is also for approval of change in address. Detail of product is as under: -

S. No.	Name of Drug (s), Composition & Reg. No. (as per approval)	Remarks
1.	Ipertrofan Enteric Coated Tablets Each tablet contains: - Mepartricin 50,000 Units Reg. No**.** 014048	Firm has submitted registration letter with complete post registration variation.

Registration Board in M-249 & M-258 approved the following products as per following details:-

M-249

S. No.	Name of Indenter/ Manufacturer	Name of drug (s)/ Composition & Therapeutic Group	Demanded Price/Pack	Shelf Life	Date of application receiving & fee.
1.	M/s. Angelini Pharmaceuticals (Pvt) Ltd. Lahore. / M/s. Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. SpA, Rome, Italy.	Trittico 75mg Prolonged-Release Tablets Each scored tablet contains:- Trazodone Hydrochloride...75mg (Antidepressants).	Rs.8.5 per prolonged release tablets pack of 30's tablets	03 years	21-03-2013 Rs.100000/-
2.	M/s. Angelini Pharmaceuticals (Pvt) Ltd. Lahore. / M/s. Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. SpA, Rome, Italy.	Trittico 150mg Prolonged-Release Tablets Each scored tablet contains:- Trazodone Hydrochloride.150mg (Antidepressants).	Rs.14.90 per prolonged release tablets pack of 20's tablets	03 years	21-03-2013 Rs.100000/-

Decision M-249:

Registration Board approved Trittico 150 mg prolonged release tablets as it is approved by USFDA and deferred Trittico 75 mg for confirmation of status of products in reference regulatory authorities.

M-258

S. No.	Name of Indenter/ Manufacturer	Name of drug (s)/ Composition & Therapeutic Group	Demanded Price/Pack	Shelf Life	Date of application receiving & fee.
1.	M/s. Angelini Pharmaceuticals (Pvt) Ltd. Lahore. / Manufacturer: M/s. Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. SpA, Rome, Italy.	Trittico 75mg Prolonged-Release Tablets Each scored tablet contains:- Trazodone Hydrochloride...75mg (Antidepressants).	Rs.8.5 per prolonged release tablets pack of 30's tablets	03 years	21-03-2013 Rs.100000/-

Decision M-258:

Registration Board deliberated the case in detail and since the formulation is already approved in Reference Regulatory Authority i.e Switzerland , so the Board approved grant of registration to Trittico 75mg Prolonged-Release Tablets, manufactured by A.Z. Chim. Ruin, Angelini Francesco Acraf SPA, Via Vecchia del Pinocchio, 22, 60131 Ancona, Italy, subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy.

The firm has submitted request with a fee of Rs.10,000/- deposited on dated 25th August 2020 of above mentioned products for change of address as per new submitted DSL before issuance of registration letter.

Decision: Keeping in view the new Drug Sale License; Registration Board decided as follows:-

a) **Approved firm's address from M/s Angelini Pharmaceuticals (Pvt) Ltd, 221-CCA, Phase 4, DHA, District Lahore to M/s Angelini Pharmaceuticals (Pvt) Ltd, Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore. Letter will be issued after confirmation of renewal status of products Brumixol Cream (Reg.No.043074) & Brumixol Ovules (Reg.No.043075).**
b) **Approved firm's address from M/s Angelini Pharmaceuticals (Pvt) Ltd, 221-CCA, Phase 4, DHA, District Lahore to M/s Angelini Pharmaceuticals (Pvt) Ltd, Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore for product Ipertrofan Enteric Coated Tablets (Reg.No. 014048).**
c) **Approved issuance of registration letter as per firm request to their new address, Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore for already approved products Trittico 75mg Prolonged-Release Tablets & Trittico 150mg Prolonged-Release Tablets**.
d) **Inspection of storage facility will be conducted for new address/ site before processing of letters.**

Case.No.10: **REQUEST OF M/S. A.J. & COMPANY, KARACHI FOR CHANGE OF PRODUCT LICENSE HOLDER FOR THEIR REGISTERED PRODUCT RECOFOL 10MG/ML (REG. NO.018502).**

M/s. A.J. & Company, Karachi has submitted request for change of Product License Holder for their already registered product Recofol 10mg/ml Reg. No.018502 as per details given below: -

Name / Composition / Reg. No.	**Existing Manufacturing Site (as per approval)**	**Proposed Site / Manufacturer & Product License Holder (as per COP)**
Recofol 10mg Injecion Each ml contains:- Propofol …… 10mg Reg. No. 018502	Marketing Authorization Holder: M/s. Primex Pharmaceuticals Oy, Mariankatu 21 C, 00170 Helsinki, Finland Manufacturer: M/s Corden Pharma S.p.A, Viale dell' Industria, n. 3 e reparto via galilei n.17 20867 Caponago MB Italy	Product Authorization Holder: M/s. Primex Pharmaceuticals AG Obmoos 4 6301 Zug Switzerland. Manufacturer: No change

The firm has submitted the following supporting documents: -

a) Fee of Rs.55,000/-+Rs.50,000/-
b) Original and legalized CoPP of the product (issued by Swissmedic).
c) Copy of Registration letter with complete post registration variation and renewal trail of the product.
d) Sole Agency Agreement.
e) Undertaking

Decision: **Registration Board approved the change of Marketing Authorization Holder of following product. Other terms and conditions will remain the same.**

Name / Composition / Reg. No.	**Previous Manufacturing Site (as per approval)**	**New approved Product License Holder (as per COP)**
Recofol 10mg Injecion Each ml contains:- Propofol …… 10mg Reg. No. 018502	**Marketing Authorization Holder:** M/s. Primex Pharmaceuticals Oy, Mariankatu 21 C, 00170 Helsinki, Finland **Manufacturer:** M/s Corden Pharma S.p.A, Viale dell' Industria, n. 3 e reparto via galilei n.17 20867 Caponago MB Italy	**Product Authorization Holder:** M/s. Primex Pharmaceuticals AG Obmoos 4 6301 Zug Switzerland. **Manufacturer:** No change

Case. No.11 **REQUEST OF MEDINET PHARMACEUTICALS, RAWALPINDI FOR CHANGE IN SPECIFICAITON & PACKAGING (DUVIG INJ REG. NO.031393).**

M/s Medinet Pharmaceuticals, Rawalpindi has submitted request that for change in finished product specifications to USP of their already registered product Duvig Injection (Dobutamine HCL 250mg) (Reg. No.031393). Specifications were not mentioned in initial registration letter dated 27-07-2004.

Change of Finished Product Specifications		
a)	Application with required fee as per relevant SRO.	Covering letter with a fee of Rs.5000/-.
a)	Copy of registration letter and last renewal status.	Copy of registration letter issued on 27-07-2004 & complete renewal trail with post registration variation trail
a)	Document in support of proposed change.	YES
b)	Original & Legalized CoPP & GMP certificate	YES
c)	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. iv. The provided information/ documents are true/ correct**.**	YES

The submitted Original CoPP is valid for twelve months which is issued on 03-12-2018, the firm has submitted copy of valid CoPP issued on 28th April, 2020 (valid for twelve months).

The firm has also submit request for change in packaging from 20ml vial to 20ml ampoule of the above mentioned product. Details are as under: -

Existing pack size	**Proposed pack size**
1' Vial	20ml x 1 Ampoule
50's Vial (Additional pack size approval letter issued on 10th Sep, 2018)	20ml x 50 Ampoule

The firm has submitted A total fee of Rs.10,000/- for approval of above subjects

Decision: Registration Board deferred for approval status of ampoule from concerned regulatory authority.

Case No.12: **CHANGE OF EXCIPIENT**

The subject case was presented & discussed in 271st meeting of Registration Board as under: -

M/s OBS Pakistan (Pvt) Limited Karachi has requested for change in excipient of their already following registered drugs:

S.No	**Reg. No**	**Name of drug(s)**	**Existing Excipient**	**Proposed Excipient**
1	009729	Pepcidine 40 mg Tablet (Famotidine)	Ethyl Alcohol	Isopropyl Alcohol

2	016865	Zocor 10 mg Tablet (Simvastatin)	do	do
3	020750	Zocor 20 mg Tablet (Simvastatin)	do	do
4	022544	Zocor 40 mg Tablet (Simvastatin)	do	do

The firm has informed that they want to change the inactive excipients (as indicated in the table above) of said products and this minor change comes due to fact that Ethyl Alcohol comes under excisable articles, and due to which they are facing lot of problems during releasing process. For that they have requested Excise and Taxation Department Karachi to discontinue their private bonded warehouse. The Excise and Taxation Department have asked to share approval letter of change in excipient from DRAP. Firm has submitted application with prescribed fee.

Decision of 271st: Keeping in view reference sent by Excise and Taxation Department, Karachi Registration Board acceded to the request of firm for use of Isopropyl Alcohol from Ethyl Alcohol

Fresh Proceedings:

Above decision was conveyed to the firm. Accordingly, a letter received from Excise, Taxation & Narcotics Control, Sindh Karachi dated 6th August, 2020 on subject i.e. usage of isopropyl alcohol instead of ethanol / rectified spirit in medicines and stated as under: -

> " I am directed to refer to your letter No. Nil dated 20-04-2020 addressed to M/s OBS Pakistan (Pvt) Ltd, Karachi. Before proceeding further this office has floated a questionnaire to M/s Pakistan Council of Scientific & Industrial Research, (PCSIR) wherein several questions were enlisted among them a question "Whether Isopropyl Alcohol can be used in the manufacturing of medicine instead of rectified spirit / ethanol" was framed. PCSIR in its report dated 07-07-2020 replied that "Isopropyl Alcohol cannot be used in the manufacturing of medicine as a raw material. However, it can be used in the sterilization / disinfection of the floors, instruments, machineries of pharmaceutical industries". In light of above report of PCSIR approval given in favor of M/s OBS Pakistan for the usage of Isopropyl Alcohol instead of rectified spirit in the manufacturing of medicine is astonishing and deserve justification to proceed further".

Decision: Registration Board advised to confirm its usage as excipient and inform Excise and Taxation Department, Karachi accordingly.

Case No.13: REGISTRATION OF DRUGS UNDER DRUGS ACT, 1976.

The subject case was presented & discussed in 288th meeting of Registration Board as under: -

B. M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. S.K. Enterprises, Office No. 701, 7th floor KS trade tower, Shahrah e Liaquat Karachi./ M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China.	SK+METROSIM Infusion Solution for IV infusion Each 100 ml contains:- Metronidazole…500mg (ANTIPROTOZOALS)	(i) Dr. FakhruddinAamir, Additional Director, Drug Regulatory Authority of Pakistan, Islamabad. (ii) Mr.Zaheer-ud-Din Muhammad Babar, Deputy Director, Drug Regulatory Authority of Pakistan, Islamabad.
		SK+CIPROSIM Injection Solution for IV Injection Each 100 ml contains:- Ciprofloxacin (as lactate)…200mg (Quinolones)	

	Manufacturer & Market Authorization Holder:- M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China. **(M-278)**	SK+RINGERSIM Infusion Solution for IV Infusion Each 500ml contains:- Sodium lactate…….1.6g Potassium chloride..0.2g Calcium chloride dehydrate….0.135g Sodium chloride……3g (electrolytes)	10th& 11th December, 2018

Comments/ Remarks of the Panel.

i. The CoPP of all the three products i.e. SK+Metrosim Infusion solution for IV infusion, SK+Ciprosim Injection solution for IV Injection and SK+Ringersim Infusion Solution for IV Infusion mentions manufacturer and product license holder as M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High & New tech Development Zone, Shijiazhuang, Hebei, China, Yangzi Road, Shijiazhunang Economic and Technological Development Zone Hebei PRC. The SK+Metrosim Infusion solution for IV infusion and SK+Ciprosim Injection solution for IV Injection are manufactured at the premises located at No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang while the product is manufactured at another premises located few streets away having address M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang, Hebei, China. However, the Quality Control and Batch release is done at the premises situated at No.288 Zhujiang Road.

ii. The management of the firm informed that the COPP are issued at the legal address, which mentions both above premises, while the GMP certificate mentions the manufacturing site and facilities. The manufacturing facility at No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang are well designed and adequately equipped having effective system and controls for cGMP compliance.

iii. The report of the premises situated at Yangzi Road, Economic and Technological Development Zone Shijiazhunang, Hebei, China., which manufactures SK+Ringersim Infusion Solution for IV Infusion, in addition to above details, states that the manufacturing facility of SK+Ringersim Infusion Solution is state of art facility and all the process from dispensing of raw material to the manufacturing of finished products are automatic with least involvement of workers. The facility have latest HVAC and WFI system. The firm claims to be the largest manufacturing of IV solutions in china. The premises appears to comply GMP requirements as observed at the time of visit.

The details regarding manufacturer / MH Holder as per Form-5A, CoPP& GMP submitted by the firm are as under:

Sr. No.	Product Name	Manufacturer / MA Holder as per Form-5A	Manufacturer / MA Holder as per CoPP	Manufacturer as per GMP
1.	SK+METROSIM Infusion Solution for IV infusion Each 100 ml contains:- Metronidazole…500mg (ANTIPROTOZOALS)	M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang, China	M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High & New tech Development Zone, Shijiazhuang, Hebei, China, Yangzi Road, Shijiazhunang Economic and Technological Development Zone Hebei PRC.	M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang,
2.	SK+CIPROSIM Injection Solution for IV Injection Each 100 ml contains:-	-do-	-do-	-do-

	Ciprofloxacin (as lactate)…200mg (Quinolones)			
3.	SK+RINGERSIM Infusion Solution for IV Infusion Each 500ml contains:- Sodium lactate…….1.6g Potassium chloride..0.2g Calcium chloride dehydrate…….0.135g Sodium chloride……3g (electrolytes)	M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang China	-do-	M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang City.

Decision:- Keeping in view the above stated position, Registration Board approved the correction in address of manufacturer in minutes of the meeting for product "*SK+RINGERSIM Infusion Solution for IV Infusion*" from "*M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China*" to "*M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang China*" in accordance with Form-5A, CoPP and GMP certificate. Furthermore, as reported by the inspection panel, quality control of product "*SK+RINGERSIM Infusion Solution for IV Infusion*" is performed by "*M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China*".

Firm will submit correct CoPP and revised Form-5A for consideration of Registration Board.

Fresh Proceedings: -

Now the firm has submitted revised Notarized copy of CoPP and Form-5A.

Decision: Registration Board deferred for legalized CoPP by Pakistan Embassy in China.

Case.No.14: STANDARDIZATION OF FORMULATION OF DECAPEPTYL 0.1MG/ML INJECTION (REG.NO.016110) IN ACCORDANCE WITH THE INNOVATOR'S PRODUCT BY M/S ATCO LABORATORIES LIMITED, KARACHI.

M/s Atco Laboratories Limited, B-18, SITE, Karachi has submitted request with a fee of Rs.5000/- that drug registration certificate of Decapeptyl 0.1mg/ml injection (Reg. No.016110) the label claim states the quantity in terms of " Each ml Contains" however, its innovator, Ferring Inc of reference regulator authority claims in terms of "each pre-filled syringe contains". Difference in existing and proposed label claim is given as under: -

Existing / approved label claim	Proposed / innovator's label claim
Decapeptyl 0.1mg/ml injection Each ml contains: Triptorelin Acetate equivalent to 95.6ug Triptorelin	Decapeptyl 0.1mg/ml injection Each pre-filled syringe of 1ml contains: Triptorelin Acetate equivalent to 95.6ug Triptorelin

Firm has submitted following supporting documents: -

- Fee of Rs.5000/-
- Notarized copy of registration letter with last renewal trail.
- Undertaking.

Firm also submitted four years Commercial invoices from 17-11-2016 to 24-05-2019, which shows, pack size 28 pcs (Syringe 1ml).

Decision: Registration Board deferred for submission of complete details of the case along with confirmation of both dosage forms presentation of the product in RRA.

Case.No.15: **REQUEST OF M/S SANOFI-AVENTIS PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Sanofi-Aventis Pakistan Limited Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered product
1.	Jumex 5mg Tablet Each film coated tablets contains:- Selegeline HCL 5mg	010215	Global decision that Sanofi has decided to withdraw the marketing authorization of jumex5mg tablet worldwide including marketing authorization registered in Hungary which is the country of origin.	1. Selgin 5mg Tablet 2. Eklin 5mg Tablet 3. Juline 5mg Tablet 4. Jumalline 5mg Tablet

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter (issued on 27-04-2018). c) Justification. d) List of alternatives brands/ FPPs available in the country. e) An undertaking that: i. No case is pending at any forum / court of law regarding this product. ii. Provided information/ documents are true/ correct.	a. Application with a fee Rs.5000/- b. Copy of registration letter c. Provided as mentioned above. d. Provided as mentioned above. e. Provided.

Decision: **Registration Board referred the case for evaluation by DRAP's availability committee.**

Case.No.16: **CORRECTION IN MINUTES FOR ALREADY APPROVED PRODUCT DAXOTEL CONCENTRATE INJECTION 20MG/ML OF M/S ATCO PHARMA (PVT) LTD, KARACHI.**

The following product of M/s Atco Pharma (Pvt) Ltd, Karachi has been approved in 259th meeting of Registration Board as under: -

Importer & Manufacturer	Brand Name & Composition	Dy. No. & Fee	Reference	Documents
M/s Atco Pharma International Pvt Ltd, B-18 S.I.T.E Karachi. Manufactured By M/s Fresenius Kabi Oncology Ltd, Villege Kishanpura, P.O Guru Majra, Tehsil Nalagarh, District Solan, India (168)	Daxotel Concentrate Injection 20mg/ml Each ml contains:- Docetaxel Anhydrous eq to Docetaxel ……20mg Anticancer Manufacturer's Specifications	Form 5A 30-10-2013 vide diary No. 274 Rs. 100,000. Rs.1200/Vial.	MHRA. Docetaxil 20mg/ml, 80mg/4ml, 160mg/8ml by M/s Dr. Reddy Local. Docetax 20mg, 80mg, 120mg by M/s A.J Mirza.	COPP valid upto 02-01-2015. GMP valid upto 02-10-2015.
Decision of 259th Meeting Approved. Firm will provide valid legalized CoPP and Chairman will permit issuance of registration letter				

The demanded MRP Rs.1200/vial mentioned in minutes is a typographically error as the demanded MRP by the firm is Rs.12000/- as per Form-5A submitted by the firm. The case is submitted for correction of demanded MRP i.e. Rs.12000/- instead of Rs.1200/-

Decision:- Registration Board deferred the case for confirmation of firm's request from original dossier.

Fresh Proceedings:-

Firm submitted a Form-5A shows MRP mentioned Rs12000/- for each vial.

Decision:- Registration Board deferred the case for confirmation of firm's request from Initial registration dossier.

Case No. 17 REQUEST OF M/S SEATLE PRIVATE LIMITED, LAHORE FOR CHANGE OF MANUFACTURING SITE FROM TOLL MANUFACTURING TO FINISHED IMPORT FOR REGISTERED PRODUCTS.

M/s Seatle Private Limited, Lahore has submitted for change of manufacturing site from toll manufacturing to finish import as per following details: -

S. No	Name & Composition (as per approval) / Reg. No.	Existing Toll Manufacturing Site	New Proposed Site / Manufacturer & Product License Holder (as per COPP)
1.	Fratazid Injection I.V. Each Vial of powder contains: - Ceftriaxone (as sodium)…500mg (USP Specification) Reg. No. 084459	M/s PharmEvo (Pvt) Ltd, A-29-North Western Industrial Zone, Port Qasim, Karachi	**Manufacturer & Product License Holder: -** LDP Laboratorios Torlan, S.A. Ctra. De Barcelona, 135-B, Cerdanyola del Valles (Barcelona) 08290 Spain
2.	Fratazid Injection I.M. Each Vial of powder contains: - Ceftriaxone (as sodium)…500mg (USP Specification) Reg. No. 084462		
3.	Fratazid Injection I.V. Each Vial of powder contains: - Ceftriaxone (as sodium)…1g (USP Specification) Reg. No. 084461		

The firm has submitted the following supporting documents: -

1. Fee of Rs. 300,000/-
2. Application on Form-5F
3. Copy of initial registration letter issued on 09-05-2017.
4. Copy **o**f COPP with free sale status of the product.
5. Copy of Eudra GMP certificate.

Decision: Registration Board advised to the firm to quote rule position in support of their subject request.

Case No. 18 **REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR CHANGE OF MANUFACTURING SITE OF THEIR EGISTERED PRODUCT.**

M/s GlaxoSmithKline Pakistan Limited, 35- Dockyard Road west Wharf Karachi has applied for change of manufacturing site of their following already registered products as per details given below: -

S. No	Reg. No.	Name & Composition (as per variation letter) (issued on 10-04-2003)	Existing approved Site Manufacturing Site (as per variation letter) (10-04-2003)	New Proposed Site / Manufacturer/ Product License Holder (as per COPP)
1.	028445	FlixotideEvohaler 50mcg Each actuation contains: Fluticasone Propionate (micronized)..50mcg	**Manufactured by:** M/s GlaxoSmithKline, France Ltd., France **Packed by:** Packaging Site: M/s Glaxo Wellcome Australia Ltd., Australia **Change in manufacturing site** (Manufacturing site: M/s Glaxo Wellcome S.A. Aranda de Duero, Spain Packaging Site: M/s GlaxoSmithKline Pty Ltd., Australia) dated 28-04-2007	**Product License Holder:** M/s GlaxoSmithKline, S.A. Severo Ochoa, 2 28760 Tre Cantos (Madrid) Spain **Manufacturer:** M/s Glaxo Wellcome S.A. Avda. Extremadura, 3 09400 Aranda de Duero (Burgos), Spain
2.	028446	FlixotideEvohaler 125mcg Each actuation contains: Fluticasone Propionate (micronized)..125mcg		
3.	028447	FlixotideEvohaler 250mcg Each actuation contains: Fluticasone Propionate (micronized)..250mcg		

The firm has submitted the following supporting documents: -

i. Fee of Rs 50,000x3=150,000/- dated 29-05-2019 additional fee 50,000x3=150,000/- dated 08-06-2020.
ii. Application on Form-5F
iii. Copy of initial registration letter dated 10-04-2003&last renewal apply dated 15-02-2018.
iv. Original & legalized COPP of Flixotide Evohaler 50mcg (No. 2019/00417) issued by department of medicines for human use showing the freely availability of product in exporting country and GMP compliant status of the product).
v. Original & legalized COPP of Flixotide Evohaler 125mcg (No. 2019/00427) issued by department of medicines for human use showing the freely availability of product in exporting country and GMP compliant status of the product). {In exporting country (Spain)applied Product status is temporary suspension of marketing authorization.}
Now the firm has submitted the Original legalized CoPP issued by MHRA UK showing the availability of applied product in exporting country.
vi. Original & legalized COPP of Flixotide Evohaler 250mcg (No. 2019/00438) issued by department of medicines for human use showing the freely availability of product in exporting country and GMP compliant status of the product).
vii. Submitted Sole agency agreement in original
viii. Undertakings that provided information are correct.

Decision: **Registration Board approved the change of Product License Holder & Manufacturer of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.**

S. No	Reg. No.	Name & Composition (as per variation letter) (issued on 10-04-2003)	Previous approved Site Manufacturing Site (as per variation letter) (10-04-2003)	New Approved Site / Manufacturer/ Product License Holder (as per COPP)

4.	028445	FlixotideEvohaler 50mcg Each actuation contains: Fluticasone Propionate (micronized)..50mcg	**Manufactured by:** M/s GlaxoSmithKline, France Ltd., France **Packed by:** Packaging Site: M/s Glaxo Wellcome Australia Ltd., Australia **Change in manufacturing site** (Manufacturing site: M/s Glaxo Wellcome S.A. Aranda de Duero, Spain Packaging Site: M/s GlaxoSmithKline Pty Ltd., Australia) dated 28-04-2007	**Product License Holder:** M/s GlaxoSmithKline, S.A. Severo Ochoa, 2 28760 Tre Cantos (Madrid) Spain **Manufacturer:** M/s Glaxo Wellcome S.A. Avda. Extremadura, 3 09400 Aranda de Duero (Burgos), Spain
5.	028446	FlixotideEvohaler 125mcg Each actuation contains: Fluticasone Propionate (micronized)..125mcg		
6.	028447	FlixotideEvohaler 250mcg Each actuation contains: Fluticasone Propionate (micronized)..250mcg		

Case No. 19 <u>REQUEST OF M/S NOVARTIS PHARMA KARACHI FOR CHANGE OF MANUFACTURING SITE OF THEIR REGISTERED PRODUCTS.</u>

M/s Novartis Pharma (Pakistan) Limited, 15 west Wharf Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 22-04-2011)	Name & Composition (as new per CoPP)	Existing approved Site Manufacturing Site (as per approval letter) (22-04-2011)	New Proposed Site / Manufacturer/ Product License Holder (asper COPP)
1.	069586	OnbrezBreezhaler 150mcg Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 150mcg	OnbrezBreezhaler Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 150mcgIndacaterol	M/s Novartis Pharma Stein AG, Switzerland	**Product License Holder:** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:** M/s Novartis Farmaceutica S.A., Ronda Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain
2.	069587	OnbrezBreezhaler300mcg Inhalation powder hard capsule 300mcg Each capsule contains: Indacaterol maleate equivalent to 300mcg	OnbrezBreezhaler Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 300mcg Indacaterol		

The firm has submitted the following supporting documents: -

a) Fee of Rs.50,000x2=100,000/- dated 20-01-2020.
b) Application on Form-5F.
c) Copy of initial registration letter & Post Registration renewal trail.
d) Original & legalized COPP (No. 09/19/136425 issued by EMA showing the freely availability of
e) product in exporting country and GMP compliant status of the product).
f) Copy of CoPP (No. 20003801 dated 14-08-2020) issued by Swiss medic showing the freely availability of product in exporting country and GMP compliant status of the product.

g) Site master file (M/s Novartis Farmaceutica).

h) Undertakings that provided information are correct.

Decision: **Registration Board approved the change of Manufacturing site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.**

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 22-04-2011)	Name & Composition (as new per CoPP)	Previously approved Manufacturing Site (as per approval letter) (22-04-2011)	New Approved Product License Holder / Manufacturer (asper COPP)
1.	069586	OnbrezBreezhaler 150mcg Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 150mcg	OnbrezBreezhaler Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 150mcgIndacaterol	M/s Novartis Pharma Stein AG, Switzerland	**Product License Holder:** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:** M/s Novartis Farmaceutica S.A., Ronda Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain
2.	069587	OnbrezBreezhaler300mcg Inhalation powder hard capsule 300mcg Each capsule contains: Indacaterol maleate equivalent to 300mcg	OnbrezBreezhaler Inhalation powder hard capsule Each capsule contains: Indacaterol maleate equivalent to 300mcg Indacaterol		

Case No.20 **REQUEST OF M/S NOVARTIS PHARMA KARACHI FOR CHANGE OF MANUFACTURING SITE & MARKETING AUTHORIZATION HOLDER OF THEIR REGISTERED PRODUCT.**

M/s Novartis Pharma (Pakistan) Limited, 15 west Wharf Karachi has applied for change of manufacturing site & Marketing Authorization Holder of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 22-03-2018)	Existing approved Site Manufacturing Site (as per approval letter) (22-03-2018)	New Proposed Site / Manufacturer/ Product License Holder (asper COPP)
1.	088393	Ultibro Breezhaler Inhalation Powder Capsule Each capsule contains: Indacaterol maleate.143mcg (eq. to 110mcg of Indacaterol) Glycopyrronium bromide.63mcg (eq to 50mcg Glycopyrronium)	**Product License Holder:** M/s Novartis Europharm Ltd, wimblehurst Road, Horsham, West Sussex RH12 5AB, UK **Manufacturer:** M/s Novartis Pharma stein AG, Schaffausertrasse, 4332 stien, Switzerland	**Product License Holder:** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:** M/s Novartis Farmaceutica S.A., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain

The firm has submitted the following supporting documents: -

a) Fee of Rs. 50,000/- dated 26-07-2019.
b) Application on Form-5F.
c) Copy of initial registration letter dated 22-03-2018.

d) Original & legalized COPP (No. 06/19/133266) dated 15-07-2019 issued by EMA showing the freely availability of product in exporting country and GMP compliant status of the product).
e) Copy of CoPP (No. 20003801 dated 14-08-2020) issued by Swiss medic showing the freely availability of product in exporting country and GMP compliant status of the product.
f) Site Master File (M/s Novartis Farmaceutica).
g) Undertakings that provided information are correct.

Decision: Registration Board approved the change of Product License Holder & Manufacturing site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

Reg. No.	Name & Composition (as per initial letter) (issued on 22-03-2018)	Previous approved Site Manufacturing Site (as per approval letter) (22-03-2018)	New Approved Product License Holder / Manufacturer (asper COPP)
088393	Ultibro Breezhaler Inhalation Powder Capsule Each capsule contains: Indacaterol maleate.143mcg (eq. to 110mcg of Indacaterol) Glycopyrronium bromide.63mcg (eq to 50mcg Glycopyrronium)	**Product License Holder:** M/s Novartis Europharm Ltd, wimblehurst Road, Horsham, West Sussex RH12 5AB, UK **Manufacturer:** M/s Novartis Pharma stein AG, Schaffausertrasse, 4332 stien, Switzerland	**Product License Holder:** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:** M/s Novartis Farmaceutica S.A., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain

Case.No.21: <u>REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LTD, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.</u>

M/s Novartis Pharma (Pakistan) Ltd, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered product
1.	Stalevo 50/12.5/200mg Film Coated Tablets Each film coated tablets contains:- Levodopa…50mg Carbidopa…12.5mg Entacapone…200mg	087625	Please note that Marketing Authorization Holder of Stalevo film-coated tablets is Orion Corporation, Finland & Novartis has terminated the license Agreements with Orion Corporation in certain markets, including Pakistan. Consequently, we will not be able import, sale or maintain the registration of this product	M/s Pharmevo (Pvt.) Ltd, Karachi **Brand Name.** Paridopa **Generic name.** Carbidopa+Levodopa+ Entacapone **Strengths.** 12.5mg+ 50mg + 200mg 25mg+ 100mg + 200mg 50mg+ 200mg + 200mg
2.	Stalevo 100/25/200mg Film Coated Tablets Each film coated tablets contains:- Levodopa…100mg Carbidopa…25mg Entacapone…200mg	087626	-do-	-do-
3.	Stalevo 150/37.5/200mg Film Coated Tablets Each film coated tablets contains:- Levodopa...150mg Carbidopa…37.5mg Entacapone…200mg	088879	-do-	-do-

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter (issued on 27-04-2018). c) Justification. d) List of alternatives brands/ FPPs available in the country. e) An undertaking that: iii. No case is pending at any forum / court of law regarding this product. iv. Provided information/ documents are true/ correct.	a. Application with a fee Rs.15000/- b. Copy of registration letter (issued on 27-04-2018). c. Provided as mentioned above. d. Provided as mentioned above. e. Provided by the firm.

Decision: Registration Board referred the case for evaluation by DRAP's availability committee.

Case.No.22: <u>REQUEST OF ELI LILLY PAKISTAN KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.</u>

M/s Eli Lilly Pakistan, Karachi has submitted request for de-registration of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered product
1.	Strattera (Atomoxetine) 10mg Capsule	043069	We would like to assure you that this De-registration is not linked by any means to safety concerns about these products; rather, Lilly is voluntarily discontinuing these products in Pakistan due to lack of demand locally.Eli Lilly Pakistan is committed to ensure fair access to innovative medications for patients across the world.	i. Autis (Atomoxetine) ii. Doqaz (Atomoxetine) iii. ADS (Atomoxetine) iv. Moxitine(Atomoxetine)
2.	Strattera (Atomoxetine) 18mg Capsule	043070		
3.	Strattera (Atomoxetine) 25mg Capsule	088871		
4.	Strattera (Atomoxetine) 40mg Capsule	043072		
5.	Strattera (Atomoxetine) 60mg Capsule	043073		

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter (issued on 12-09-2006). c) Justification. d) List of alternatives brands/ FPPs available in the country. e) An undertaking that: i. No case is pending at any forum / court of law regarding this product. ii. Provided information/ documents are true/ correct.	a. Application with a fee Rs.25000/- b. Copy of registration letter c. Provided as mentioned above. d. Provided as mentioned above. e. Provided by the firm.

Decision: Registration Board referred the case for evaluation by DRAP's availability committee.

Case No. 23 REQUEST OF M/S PFIZER PAKISTAN LIMITED 12-DOCKYARD ROAD, WEST WHARF, KARACHI FOR CHANGE OF MANUFACTURING AND PACKAGING SITE OF THEIR UNDER REGISTERED PRODUCT.

M/s Pfizer Pakistan Limited suit no. 1, 12-Dockyard Road, west wharf, Karachi has applied for change of Manufacturing and packaging site of their following under registered products as per details given below:-

S. No	Name & Composition (as per 238th meeting of RB)	Existing approved Sites (as per 238th meeting of RB)	New Proposed sites (as per COPP)
1.	Eliquis Film Coated Tablets Each tablet contains:- Apixaban……2.5mg Anti-thrombotic agent (Factor Xa Inhibitor)	**Manufactured by :-** Bristol-Myers Squibb Manufacturing Company Humacao, Puerto Rico, USA. **Packaged & released by:** M/s. Bristol-Myers Squibb S.r.I Loc. Fontana del Ceraso Anagni (FR), Italy..	**Marketing Authorization Holder:** M/s **Bristol-Mayers** Squibb/**Pfizer** EEIG, Plaza 254, Blanchardstown corporate Park 2, Dublin 15, D 15 T 867, Ireland. **Manufacturer:** M/s Pfizer Ireland Pharmaceuticals, Little Connell newbridge, Co. Kildare, Ireland **Primary & Secondary packaging:** M/s Pfizer manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany (Release site as per firm submitter letter)
2.	Eliquis Film Coated Tablets Each tablet contains:- Apixaban…….5mg Anti-thrombotic agent (Factor Xa Inhibitor)	**Manufactured by :-** Bristol-Myers Squibb Manufacturing Company Humacao, Puerto Rico, USA. **Packaged & released by:** M/s. Bristol-Myers Squibb S.r.I Loc. Fontana del Ceraso Anagni (FR), Italy.	

The firm has submitted the following supporting documents: -

a) Application on Form-5-F
b) Fee of Rs.100,000/- (Rs. 50,000 for each product)
c) Copy of DSL valid upto 06-06-2020 submitted renewal dated 11-06-2020
d) Original & legalized COPP for Apixaban 2.5mg (No. 06/19/139816) & for Apixaban 5mg (No. 01/19/139817) issued by EMA.
e) Original Sole agency agreement.
f) Original & legalized GMP issued by Health Authorities of Germany and Ireland.
g) Site master file.
h) Undertaking that the provided information/ documents are true/correct.

Decision: Registration Board approved the change of Marketing Authorization Holder, Manufacturer & Primary & Secondary Packaging site of following products (under-registration) subject to policy for inspection of manufacturer abroad of imported drugs.

S. No	Name & Composition (as per 238th meeting of RB)	Previous approved Sites (as per 238th meeting of RB)	New Approved sites (as per COPP)
1.	Eliquis Film Coated Tablets Each tablet contains:- Apixaban……2.5mg Anti-thrombotic agent (Factor Xa Inhibitor)	**Manufactured by :-** Bristol-Myers Squibb Manufacturing Company Humacao, Puerto Rico, USA. **Packaged & released by:** M/s. Bristol-Myers Squibb S.r.I Loc. Fontana del Ceraso Anagni (FR), Italy..	**Marketing Authorization Holder:** M/s **Bristol-Mayers** Squibb/**Pfizer** EEIG, Plaza 254, Blanchardstown corporate Park 2, Dublin 15, D 15 T 867, Ireland. **Manufacturer:**

2.	Eliquis Film Coated Tablets Each tablet contains:- Apixaban…….5mg Anti-thrombotic agent (Factor Xa Inhibitor)	**Manufactured by :-** Bristol-Myers Squibb Manufacturing Company Humacao, Puerto Rico, USA. **Packaged & released by:** M/s. Bristol-Myers Squibb S.r.I Loc. Fontana del Ceraso Anagni (FR), Italy.	M/s Pfizer Ireland Pharmaceuticals, Little Connell newbridge, Co. Kildare, Ireland **Primary & Secondary packaging:** M/s Pfizer manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany (Release site as per firm submitter letter)

CASE.NO.24: <u>REQUEST FOR CHANGE OF PACKAGING SITE BY M/S PFIZER PAKISTAN LIMITED, 12-DOCKYARD ROAD KARACHI</u>.

M/s Pfizer Pakistan Limited 12-Dockyard Road, West Wharf, Karachi has applied for change in Packaging Site for their following registered products as per details given below:

S. #	Reg. No.	Name &Composition	Existing approved sites(as per approval letter dated 29-10-2015)	New Proposed Sites as per COPP
1.	041196	Zeldox 40mg Capsules Each Capsule contains: Ziprasidone HCl 40mg	**Bulk Manufacturer & testing site:** Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Republic of Ireland **Packaging and Labeling, testing and Batch release:** R-Pharm Germany GmbH, Heinrich-Mack-Str. 35, 89257 Illertissen Germany	**Product License Holder:** M/s Pfizer Pharma PFE GmbH Linkstrasse 10 10785 Berlin Germany **Manufacturing & testing site:** (Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Republic of Ireland (<u>NO CHANGE</u>) **Packaging and Labeling, testing and Batch release:** Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1, 79090 Freiburg, Germany
2.	045682	Zeldox 60mg Capsules Each Capsule contains: Ziprasidone HCl 60mg		

The firm has submitted the following supporting documents for each product:-

a) Application on Form-5-F submitted on November 13, 2019
b) Fee of Rs.100,000/-(Rs. 50,000 for each product) Additional Fee of Rs.100,000/- (Rs. 50,000 for each product) Paid 4th June 2020.
c) Registration letters (issued on 40mg: 27th Mar, 2006, 60mg: 5th Jun, 2007) (last renewal 15-06-2016)
d) Original & legalized COPP (Zeldox 40mg no. 015113 & Zeldox 60mg No. 015115) issued by Landesamt fur Gesundheit und Soziales Berlin Deutschland dated 25th April 2019.
e) Sole agency agreement
f) Site master file.
g) Undertaking that the provided information/ documents are true/correct.

Decision: Registration Board approved the change of Packaging site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

S. #	Reg. No.	Name & Composition of Product	Previous approved sites (as per approval letter dated 29-10-2015)	New Approved Sites (As per COPP)
1.	041196	Zeldox 40mg Capsules Each Capsule contains: Ziprasidone HCl 40mg	**Bulk Manufacturer & testing site:** Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Republic of Ireland **Packaging and Labeling, testing and Batch release:** R-Pharm Germany GmbH, Heinrich-Mack-Str. 35, 89257 Illertissen Germany	**Product License Holder:** M/s Pfizer Pharma PFE GmbH Linkstrasse 10 10785 Berlin Germany **Manufacturing & testing site:** (Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Republic of Ireland (NO CHANGE) **Packaging and Labeling, testing and Batch release:** Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1, 79090 Freiburg, Germany.
2.	045682	Zeldox 60mg Capsules Each Capsule contains: Ziprasidone HCl 60mg		

CASE. NO.25: REQUEST FOR CHANGE OF MANUFACTURING AND PACKAGING SITES BY M/S WYETH PAKISTAN LIMITED KARACHI

M/s Wyeth Pakistan Limited, Room No. 002 & 003, SITE., Karachi has applied for change in Manufacturing and Packaging Site for their following registered products as per details given below:

Reg. No.	Name & Composition	Existing approved sites	New Proposed Sites as per COPP
031376	Rapamune 1mg Tablets Each Tablets contains: Sirolimus 1mg	**Manufacturer: (dated 22-07-2004)** Wyeth Pharmaceuticals Company Guyama, Puerto Rico, USA **Packaging site: (dated 26-03-2005)** M/s Wyeth Taiwan Corporation no. 290-1, Chung Lun, Chung lun village Hsinfeng, Hsin Chu, Taiwan	**Marketing Authorization Holder:** M/s Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium **Manufacturer:** M/s Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Ireland **Primary & Secondary Packaging:** Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg Mooswaldallee 1, 79090 Freiburg, Germany (Batch Release site as perform-5F)

The firm has submitted the following supporting documents for each product:-

a) Application on Form-5-F
b) Fee of Rs.100,000/-
c) Registration letters & last renewal **(last renewal date 20-03-2015)**
d) Original & legalized COPP (No. 02/19/134100) issued by EMA.
e) Sole agency agreement
f) Site master file of respective sites.
g) Undertaking that the provided information/ documents are true/correct.

Decision: Registration Board approved the change of Manufacturing & Packaging site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

Reg. No.	Name & Composition	Previous approved sites (as per approval)	New approved Sites (as per COPP)
031376	Rapamune 1mg Tablets Each Tablets contains: Sirolimus 1mg	**Manufacturer:** **(dated 22-07-2004)** Wyeth Pharmaceuticals Company Guyama, Puerto Rico, USA **Packaging site:** **(dated 26-03-2005)** M/s Wyeth Taiwan Corporation no. 290-1, Chung Lun, Chung lun village Hsinfeng, Hsin Chu, Taiwan	**Marketing Authorization Holder:** M/s Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium **Manufacturer:** M/s Pfizer Ireland Pharmaceuticals, Little Connell, Newbridge, Co. Kildare, Ireland **Primary & Secondary Packaging:** Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg Mooswaldallee 1, 79090 Freiburg, Germany (Batch Release site as perform-5F)

Case No.26 <u>REQUEST OF M/S ACTO LABORATORIES LIMITED FOR CHANGE OF MANUFACTURING SITE AND MARKETING AUTHORIZATION HOLDER OF REGISTERED PRODUCT.</u>

M/s Atco Laboratories Limited B-18, S.I.T.E, Karachi has applied for change of manufacturing site and Marketing Authorization Holder of their following already approved product in 283rd meeting of Registration board as per details given below: -

Name & Composition	Existing approved Site Manufacturing Site(as per 283rd meeting of Registration Board)	New Proposed Site / Manufacturer/ Product License Holder (asper COPP)
Brinavess 20mg/ml Concentrate for Solution for Infusion. Each 25ml vial contains: Vernakalant Hydrochloride 500mg eq. 452.5mg vernakalant	Product License Holder: M/s Cardiome UK Limited, Lakeside House, 1 Furzeground Way, Stockley Park, Uxbridge, Middlesex, UB11 1BD, United Kingdom Drug Product Manufacturing Site + Primary Packaging M/s Hameln Pharmaceuticals Gmbh, Langes Feld 13, 31789, Germany Drug Product Batch Release+ Secondary Packaging: M/s Geodis Logistics Netherlands B.V., Columbusweg 16, 5928 LC Venlo, The Netherlands	**Product License Holder**: M/s Correvio, 15 rue du Bicentenaire, 92800 Puteaux, France **Manufacturer/ Primary Packaging:** M/s Siegfried Hameln GmbH Langes Feld 13 31789 Hameln Germany **Drug Product Batch Release+ Secondary Packaging:** M/s Geodis Logistics Netherlands B.V., Columbusweg 16, 5928 LC Venlo, The Netherlands

The firm has submitted the following supporting documents: -

a) Fee of Rs.100,000/- dated 13-01-2020
b) Application on Form-5F
c) Copy of minutes of 283rd meeting of Registration Board.
d) Original & legalized COPP (No. 02/18/124964 issued by EMA dated 10-10-2018 showing the freely availability of product in exporting country and GMP compliant status of the product).
e) Submitted stability data at 30^0C/65%RH for 36 months and accelerated 6 months at 40^0C/75%RH
f) Site master file (M/s Siegfried Hameln GmbH Langes Field 13 31789 Hameln Germany)

Remarks of Evaluator:

- Sole agency agreement/Authorization letter is not submitted from Product License Holder.

Decision: Registration Board acceded the firm's request and deferred for submission of Sole Agency Agreement / Authorization letter from Product License Holder.

Case.No.27: <u>REQUEST OF M/S ROCHE PAKISTAN LIMITED, KARACHI FOR CHANGE OF MANUFACTURING SITE & MARKETING AUTHORIZATION HOLDER OF THEIR REGISTERED PRODUCT TARCEVA 100MG & 150MG FC TABLET.</u>

M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi has applied for change of manufacturing site & marketing authorization holder of their following already registered product as per details given below: -

S. No	Reg. No	Name & Composition (as per initial letter) (issued on 22-03-2006)	Existing approved Site Manufacturing Site (as per approval letter) (14-12-2016)	New Proposed Site / Manufacturer (as per COPP)
1	043002	Tarceva 100mg Tablets Each film-coated tablet contains: Erlotinib hydrochloride corresponding to 100mg of Erlotinib	**Manufacturer:** M/s. F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel Switzerland	**Product License Holder:** Roche Pharma (Schweiz) AG, Gartenstrasse 9, CH-4052, Basel, Switzerland **Manufacturer:** Delpharm Milano S.r.l. Via Carnevale, 1 20090, Segrate (Milano), Italy
2.	043003	Tarceva 150mg Tablets Each film-coated tablet contains: Erlotinib hydrochloride corresponding to 150mg of Erlotinib		

The firm has submitted documents as per following details: -

a) Fee of Rs.100,000/-.
b) Application on Form-5F
c) Copy of initial registration letter & Post Registration renewal trail (last renewal 21-03-2016).
d) Original& legalized COPP (Tarceva 100mg No.19006971 & Tarceva 150mg No. 19006972) Issued by Swissmedic dated 13-12-2019.
e) Copy of Sole Agency Agreement.
f) Undertaking.

Decision: Registration Board approved the change of Manufacturing site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

S. No	Reg. No	Name & Composition (as per initial letter) (issued on 22-03-2006)	Previous approved Manufacturing Site (as per approval letter) (14-12-2016)	New Approved Product License Holder / Manufacturer (as per COPP)
1	043002	Tarceva 100mg Tablets Each film-coated tablet contains: Erlotinib hydrochloride corresponding to 100mg of Erlotinib	**Manufacturer:** M/s. F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel Switzerland	**Product License Holder:** Roche Pharma (Schweiz) AG, Gartenstrasse 9, CH-4052, Basel, Switzerland **Manufacturer:** Delpharm Milano S.r.l. Via Carnevale, 1 20090, Segrate (Milano), Italy
2.	043003	Tarceva 150mg Tablets Each film-coated tablet contains: Erlotinib hydrochloride corresponding to 150mg of Erlotinib		

Case No.01: Cases Deferred by Registration Board.

M-295

i. Extension in Contract Manufacturing of Registered Drugs.

The following firms have submitted applications for extension in manufacturing of registered drugs on contract basis.

Sr.#	Name of Drug(s) with composition; Reg.No. & Name of Contract Manufacturer / Dy.No.(R&I) & date	Date of Reg. & variations	Registration / Post Reg. Variation History	Documents submitted/ Remarks	Decision of 295th Meeting of Registration Board
a.	**M/s Akhai Agencies,** Akhai Arcade, 2nd Floor, 103-K, Block-2, PECHS, Shahra-e-Quaideen, Karachi. **Contract Manufacturer: M/s ICI Pakistan Ltd, Hattar.** (Formerly: M/s Cirin Pharmaceutical (Pvt.) Ltd,**)**				
1.	Tricort 40mg Injection (IM) Each ml contains: Triamoinolone Acetonide……40mg (Reg.No.019478) *Dy.No.8653 (R&I) dated 22-Apr-2020*	**18-Aug-96** **10-Apr-07** **24-Jul-08** **13-Jul-09** **19-Sep-13** **15-Oct-15**	Initial registration. Transfer of registration from import to local manufacturing by M/s Cirin Pharma, Hattar vide letter No.F.24-4/07-Reg-II (North) **till 08-Apr-08**. Extension granted vide letter No.F.13-1/08-Reg-II (M-212) **till 23-Jul-09.** Extension granted vide letter No.F.11-20/08-Reg-II (North) **till 30-Jun-2010.** **Interim Extensions granted from 1-Jul-10 to 31-Aug-13.** Extension granted vide letter No.F.3-2/13-Reg-II (M-238) **till 30-Jun-2015**. Last Extension of Contract Manufacturing granted vide letter No.F.3-4/15-Reg-II (M250) **till 30-Jun-2020**.	Fee Rs.50,000/-**(17-Mar-20)** for each product. Copies of initial registration letter & extensions. Undertaking. Copy of agreement b/w contract giver/acceptor. Copies of DSL/DML of contract giver/acceptor. Copy of Section approval of manufacturer. Name/Title of manufacturer has been changed from M/s Cirin Pharmaceuticals (Pvt.) Ltd., Hattar to M/s ICI Pakistan Ltd, Hattar vide letter No.F.3-4/92-Lic (Vol-III) dt: 18th & 20th February, 2020. However, manufacturing site remains same.	Registration Board observed that title of M/s Cirin Pharmaceuticals (Pvt.) Ltd. has been changed to M/s ICI Pakistan Ltd previously. The Board deferred and advised to confirm whether M/s Akhai has applied for change of title of manufacturer or otherwise and manufacturing status of these products during this period.
2.	Nuphine 10mg Injection (IM/IV) Each ml contains: Nalbuphine HCl…10mg (Reg.No.021016) *Dy.No.8649 (R&I) dt: 22-Apr-2020*	**25-Apr-98** **10-Apr-07** **24-Jul-08** **13-Jul-09** **19-Sep-13** **15-Oct-15**	Initial registration. Transfer of registration from import to local manufacturing by M/s Cirin Pharma, Hattar vide letter No.F.24-4/07-Reg-II (North) **till 08-Apr-08**. Extension granted vide letter No.F.13-1/2008-R-II (M-212) **till 23-Jul-09.** Extension granted vide letter No.F.11-20/2008-Reg-II (North) **till 30-Jun-2010.** **Interim Extensions granted from 1-Jul-10 to 31-Aug-13.** Extension granted vide letter No.F.3-2/2013-Reg-II (M-238) **till 30-Jun-2015**. Last Extension of Contract Manufacturing granted vide		
3.	Nuphine 20mg Injection (IM/IV) Each ml contains: Nalbuphine HCl…20mg (Reg.No.021017) *Dy.No.8654 (R&I) dt: 22-Apr-2020*				

			letter No.F.3-4/2015-Reg-II (M250) **till 30-Jun-2020**.		
b.	**M/s Akhai Pharmaceuticals, Akhai Arcade, 4th Floor, 103-K, Block-2, P.E.C.H.S., Shahra-e-Quaideen, Karachi. Contract Manufacturer: M/s ICI Pakistan Ltd, Hattar.** (Formerly: M/s Cirin Pharmaceutical (Pvt.) Ltd,**)**				
4.	S-Choline Injection Each 2ml contains: Suxamethonium Chloride ……..100mg (Reg.No.017411) *Dy.No.8648 (R&I)* *dt: 22-Apr-2020*	**13-Jul-95** **6-Jun-97** **16-Jul-97** **10-Apr-07** **24-Jul-08** **13-Jul-09** **19-Sep-13** **15-Oct-15**	Initially registered in the name of M/s Asian Agencies, Kchi Change of brand name from Muscholine to S-Choline. Transfer of registration from M/s Asian Agencies to M/s Akhai Pharmaceuticals vide letter No.F.1-21/97-Reg-I. Transfer of registration from import to local on contract manufacturing by M/s Cirin Pharma, Hattar vide letter No.F.24-4/07-Reg-II (North) **till 09-Apr-08**. Extension granted vide letter No.F.13-1/08-Reg-II (M-212) **till 08-Jul-09.** Extension granted vide letter No.F.11-20/08-Reg-II (North) **till 30-Jun-2010.** **Interim Extensions granted from 1-Jul-10 to 31-Aug-13.** Extension granted vide letter No.F.3-2/13-Reg-II (M-238) **till 30-Jun-2015.** Last Extension of Contract Manufacturing granted vide letter No.F.3-4/15-R-II (M-250) **till 30-Jun-20**	• Fee Rs.50,000/- **(17-Mar-20**) for each product. • Copies of initial reg. letters & extensions. • Undertakings. • Copy of agreement b/w contract giver/acceptor. • Copy of DML of contract acceptor. • Copy of Section approval of manufacturer. **Remarks:** • The Name/Title of manufacturer has been changed from M/s Cirin Pharmaceuticals (Pvt.) Ltd., Hattar to M/s ICI Pakistan Ltd, Hattar vide letter No.F.3-4/92-Lic (Vol-III) dated 18th & 20th February, 2020. However, manufacturing site remains the same.	Registration Board observed that title of M/s Cirin Pharmaceuticals (Pvt.) Ltd. has been changed to M/s ICI Pakistan Ltd previously. The Board deferred and advised to confirm whether M/s Akhai has applied for change of title of manufacturer or otherwise and manufacturing status of these products during this period.
5.	Hydrocort 250mg Injection Each vial contains: Hydrocortisone (as Sodium succinate) ……..…250mg (Reg.No.015750) *Dy.No.8651 (R&I)* *dt: 22-Apr-2020*	**7-Sep-94** **10-Apr-07** **24-Jul-08** **13-Jul-09** **19-Sep-13** **15-Oct-15**	Initial registration. Transfer of registration from import to local on contract manufacturing by M/s Cirin Pharma, Hattar vide letter No.F.24-4/07-Reg-II (North) **till 09-Apr-08**. Extension granted vide letter No.F.13-1/08-Reg-II (M-212) **till 08-Jul-09.** Extension granted vide letter No.F.11-20/08-Reg-II (North) **till 30-Jun-2010.** **Interim extensions granted from 1-July-10 to 31-Aug-13** Extension granted vide letter No.F.3-2/13-Reg-II (M-238) **till 30-Jun-2015.** Last Extension of Contract Manufacturing granted vide		
6.	Hydrocort 100mg Injection Each vial contains: Hydrocortisone (as Sodium succinate) ……100mg (Reg.No.015751) *Dy.No.8652 (R&I* *dt: 22-Apr-2020*				

			letter No.F.3-4/15-R-II (M250) **till 30-Jun-2020**.		
7.	Flucate 25mg Injection Each ml contains: Fluphenazine Decanoate……..25mg (Reg.No.016317) *Dy.No.8650 (R&I) dt: 22-Apr-2020*	**8-Dec-94** **10-Apr-07** **24-Jul-08** **13-Jul-09** **Interim extensions granted from 1-July-10 to 31-Aug-13** **19-Sep-13** **15-Oct-15**	Initial registration. Transfer of registration from import to local on contract manufacturing by M/s Cirin Pharma, Hattar vide letter No.F.24-4/07-Reg-II (North) **till 09-Apr-08**. Extension granted vide letter No.F.13-1/08-Reg-II (M-212) **till 08-Jul-09.** Extension granted vide letter No.F.11-20/08-Reg-II (North) **till 30-Jun-2010.** Extension granted vide letter No.F.3-2/13-Reg-II (M-238) **till 30-Jun-2015.** Last Extension of Contract Manufacturing granted vide letter No.F.3-4/15-R-II (M250) **till 30-Jun-2020**.		

As per decision of 295th meeting of Registration Board regarding grant of authorization to Chairman, Registration Board to grant extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.

The cases were presented in 45th meeting of Post Registration Variation Committee (PRVC) for the grant of extension in contract manufacturing of already registered products of M/s Akhai Agencies, Karachi & M/s Akhai Pharmaceuticals, Karachi on the same terms and conditions after submission of fee of Rs.50,000/- dated 12th August, 2020 for the change of title/name of manufacturer from M/s Cirin Pharmaceuticals (Pvt.) Ltd to M/s ICI Pakistan (site remains the same) and the Chairman, Registration Board decided as under;

Decision of 45th meeting of PRVC: The Chairman, Registration Board decided as under;

i. Approved the request of firm for the change of title of manufacturer from M/s Cirin Pharmaceuticals (Pvt.) Ltd. to M/s ICI Pakistan Ltd., (Site remains the same).
ii. Also approved the request of firm for extension in contract manufacturing from M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar on the same terms & conditions for five years w.e.f. 1-July-2020 to 30-June-2025.

Further, Chairman also directed that the Registration Board may be intimated for the same, accordingly.

Decision: Registration Board noted the information.

ii. Change of Manufacturer of Bulk Import Source of Registered Drugs of M/s Martin Dow Limited, Karachi.

M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has requested for change of manufacturer of Bulk Import Source of their following registered drugs from M/s Cenexi SAS, France to M/s Siegfried Hameln GmbH, Germany as per details below;

Sr. No.	Name of Drug(s) with Composition & Reg.No.	Date of initial Reg. & Renewal Status	Existing Manufacturer of Bulk Source Import	Proposed Manufacturer of Bulk Source Import	Documents Submitted & Remarks (if any)
1.	Lidocaine 1% (2ml)		Manufacturer:		

	Each ml solvent contains: Lidocaine Hydrochloride.....10mg (in form of lidocaine HCl monohydrate 10.66mg) (USP specification) (Reg.No.045355)	15-May-07 Renewal 22-Jun-16 & 15-Apr-19 (Fee Rs.20,000/-) for each product	M/s Cenexi SAS, Fontenary, Sous Bois, France Marketing Authorization: M/s F.Hoffman La Roche, Basel, Switzerland.	M/s Siegfried Hameln GmbH, Langes Feld 13 31789 Hameln, Germany	➢ Fee Rs.100,000/-**(13-Dec-19)** for each product ➢ CTD dossiers for each product ➢ Copies of initial Reg.letters and last renewal status. ➢ Original/legalized of CoPP of M/s Siegfried Hameln GmbH, Germany. ➢ Original/legalized GMP of new manufacturing site. ➢ Original/legalized license of new manufacturing site ➢ Site Master File for new manufacturing site ➢ Agreement ➢ Termination letter from previous manufacturer. ➢ Undertaking.
2.	Lidocaine 1% (3.5ml) Each ml solvent contains: Lidocaine Hydrochloride…….10mg (in form of lidocaine HCl monohydrate 10.66mg) (USP Specification) (Reg.No.045356)				
3.	Water for Injection (5ml) Each ampoule contains: Sterilized water for Injections…….5ml (Eur. Ph. Specification) (Reg.No.045353)				
4.	Water for Injection (10ml) Each ampoule contains: Sterilized water for Injections …….10ml (Eur. Ph. Specification) (Reg.No.045354)				

Remarks:

Firm not provided documents pertaining to Drug Substance part in Module 3 while documents pertaining to Drug Product part was complete. The Reason/Justification provided was *"being diluents (of Ceftriaxone injection) manufacturer performed all studies on FPP rather than Drug Substance. Hence DMF related part was not included"*

Further, the title/name of firm has also been changed from M/s Martin Dow Pharmaceuticals Limited to M/s Martin Dow Limited (DML No.000267-Formulation) vide Licensing Division's letter No.F.6-4/2014-Lic (M-235) dated 30th June, 2014 (Manufacturing site remains the same) and the firm has also requested for the change of title /name of firm for the above mentioned products.

Decision of 295th Meeting of Registration Board:

Registration Board deferred for provision of information regarding quality control release of the products.

Updated Submission:

The firm has submitted that they will perform testing & quality control release of the above-mentioned products at their licensed premises i.e. M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi.

Decision: Registration Board acceded to request of M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi for change of bulk manufacturer of their registered drugs from M/s Cenexi SAS, France to M/s Siegfried Hameln GmbH, Germany. However, repacking and quality control release will be performed at M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi.

iii. Request for change of manufacturing site of registered product of M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, S.I.T.E Karachi

M/s ICI Pakistan Ltd, Karachi has requested for change of manufacturing site of their following registered products from M/s Pfizer Pakistan Ltd, Karachi to their own.

S.#	Reg. No.	Name of Product with Composition	Remarks
1	097003	Citralka Liquid Each 5ml contains: Disodium Hydrogen Citrate……1.315g (As per innovator's specifications)	Stability data (both accelerated and real time studies) submitted for 6 months. Being titrimetric analytical method, chromatograms are not applicable.

In this regard, the firm has submitted the following documents;

i. Application on Form-F along-with Fee of Rs.20,000/- (Dated 20-Nov-19)
ii. Copies of Initial Registration letter dated 28th June, 2019.
iii. Evidence of Section approval by CLB dated 28th June, 2019.

M/s ICI Pakistan Limited acquired the registration of Citralka Liquid from Pfizer Pakistan Limited under an Asset Purchase Agreement dated 19th May 2017. Subsequently, ICI Pakistan Limited applied for transfer of registration and contract manufacturing permission for local manufacturing on 15th March 2018.

Registration Board approved Citralka registration in the name of ICI Pakistan Limited on contract manufacturing basis by Pfizer Pakistan Limited in its 284th meeting and approval letter was issued after completion of other formalities on 28th June 2019.

The case was discussed in 295th meeting of Registration Board and decided as follows:

Decision 295th meeting: Registration Board deferred for evaluation of registration application and completion of documents as per Form5F.

Application of firm was reassessed. Documents were deficient as per Form5F which were communicated vide letter No. F.295-RB/2020 (PR-1) dated 13.08.2020. The reply was reassessed and deficiencies were again communicated vide letter No. F 1-1/2020-PR-1 (Deficiency) dated 25.08.2020 and reply was submitted as follows:

1) Documents for the procurement of API in the name of ICI Pakistan Limited, Karachi are required. Since MA holder as well as manufacturer will be ICI Pakistan Limited Karachi

Submission:
As the current manufacturer, Pfizer Pakistan procured the API for manufacture of Citralka. ICI Pakistan Limited acquired API of Citralka from Pfizer Pakistan to conduct its stability as the same product will be manufactured by ICI Pakistan Limited, following DRAP approval.

2) The result of verification studies of drug substance performed by the drug product manufacturer is not submitted in section 3.2.S.4.3.

Submission:
Analytical method verification of drug substance has been submitted by ICI Pakistan Limited, Karachi.

3) Submit results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture

Submission
Certificate of Analysis of relevant batch (i.e. 42181212) of Drug Substance performed by ICI Pakistan, Limited is submitted.

4) Submit real time stability study data of drug substance in section 3.2.S.7 conducted as per zone IV-A conditions

Submission:
Real time stability data of drug substance is not as per zone IV-A condition. In the light of decision of Registration Board 290th meeting following data is required:

- Record of data logger for the storage conditions throughout the transportation.
- Real term stability studies data of the product for at least 1 year along with degradation studies in the finished pharmaceutical product

Firm had performed real time stability data for the period of 12 months as per zone IV-A conditions. Moreover, firm has submitted degradation studies performed on a single batch T-01 at 50°C for the period of 24 hours. Parameters studied were description/physical appearance, PH and Assay.

Firm has submitted undertaking to continue stability studies along with degradation/stress studies throughout the shelf life of product and results will be communicated.

Regarding data logger for storage conditions firm has submitted declaration from API manufacturer that storage condition of material is STORE IN TIGHTLY CLOSED CONTAINER PROTECTED FROM SUNLIGHT. Further it is stated that temperature control is not required.

5) Submit data of pharmaceutical equivalence of the applied drug with the innovator / reference / comparator product.

Submission:

Firm has submitted pharmaceutical equivalence data in comparison with reference product manufactured at M/s Pfizer Pakistan Ltd, Karachi. The parameters studied were description/physical characteristics, PH and Assay. Results of three batches (T-01, T-02 & T-03) were comparable with results of studied batches of reference product.

Decision: Registration Board acceded to request of M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, S.I.T.E Karachi for change of manufacturing site of their registered product i.e Citralka Liquid (Reg. No. 097003) from M/s Pfizer Pakistan Ltd, Karachi to their own site i.e. M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, S.I.T.E. Karachi.

M-289

iv. Change of Registration Status from Import to Local Manufacturing by M/s Abbott Laboratories (Pakistan) Ltd, Karachi.

Dy.No.11968 (R&I) dated: 2-Apr-18

M/s Abbott Laboratories (Pakistan) Ltd, Karachi have requested for transfer of their following registered product from finished import to local manufacturing. The details are as under;

Sr. No.	Reg. No	Name of Drug(s) & Composition	Existing Manufacturer	Proposed Source of Manufacturer of Pellets	Proposed Formulation and repacking site
1	009192	**Froben SR Capsule** Each capsule contains: Flurbiprofen sustained release pellets…200mg	M/s. Famar, L'Aigle, France	Alphamed Formulations Pvt. Ltd. Sy. No.225, Sampanbole Village Shamirpet Mandal, Medchal –Malkargiri District Telangana-500078, India.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi

The firm has submitted following documents:

1. Fee of Rs. 100,000/- **(2-Apr-18)** deposited.
2. Application on Form-5.
3. Copy of initial registration (28-Jul-1986) letter and renewal confirmed from RRR Section.
4. cGMP of Pellets Manufacturing Site (Valid till 08-May-2020).
5. Stability Data of Pellets (Zone IV-A) Real & Accelerate time.
6. Certificate of Analysis of Pellets.
7. Undertaking regarding impact of Shelf life.

Decision of 289th meeting of Registration:

Registration Board deferred the request of firm for NOC from marketing authorization holder / manufacturer.

Updated Submission: *Dy.No.48 (PR-I) dated 8-July-2020*

Now, the firm has submitted original NOC (legalized) dated 19.02.2020 from manufacturer of Froben SR Capsules i.e. M/s Famar L' Agile, France dully attested by Pakistan Embassy-France.

Decision: Registration Board acceded to request of M/s Abbott Laboratories (Pakistan) Ltd, Karachi for change of registration status of their registered product i.e. Froben SR Capsule (Reg. No. 009192) from finished import to local manufacturing at M/s Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.

Case No.02: Cases Referred by Post Registration Variation Committee (PRVC).

37-PRVC

i. Change of Finished Product Specification of Registered Drug (s).

The following products of M/s MKB Pharmaceuticals (Pvt.) Ltd, Plot #66, Hayatabad Industrial Estate, Peshawar for the change of finished product specifications of registered drugs were discussed in 37th meeting of PRVC. The details are as under;

Sr.#	Reg. No.	Name of Drug(s) with composition & specification	Proposed Specification	Justification	Remarks
1.	046864	Mobilex 7.5mg Tablets Each tablet contains: Meloxicam……7.5mg **(BP Specification)**	USP Specification	BP method shows interference in results with our excipients due to which peak resolution is not good enough. In USP method, there is no such interference found. In BP monograph for assay, mixing time for sample preparation is **03 hours,** however, in USP monograph its just 30 minutes. In USP monograph sample concentration for 7.5mg and 15mg tablets are mentioned, which creates any easy approach to follow instructions for sample preparation. In USP, product is tested on isocratic HPLC system and in BP its now gradient which is more time consuming.	Assay limit in USP: 90-110% Assay limit in BP: 95-105%
2.	046865	Mobilex 15mg Tablets Each tablet contains: Meloxicam……..15mg **(BP Specification)**	USP Specification		Assay limit in USP: 90-110% Assay limit in BP: 95-105%
3.	086480	Nerish 500mcg Tablets Each sugar coated tablet contains: Mecobalamin…….500mcg **(JP Specification)**	USP Specification	In JP monograph, injection volume is 10uL, due to this low injection volume our standard RSD% for 5 injections is always greater than 2.0%. In USP monograph, injection volume is 50uL, and RSD% for 5 standard injection is under 1.0%. In JP method our excipients interferes with active drug peak areas due to which peaks areas are fused. In USP method acitive drug peak areas are clear. Our samples are showing uniform results in	Mecobalamin tablet is available in Dietary USP.

				Mobile phase as mentioned in USP monograph while the procedure as mentioned in JP monograph, which involves dilution of samples with water & methanol is not giving satisfactory results.	

Decision of 37-PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board decided as follows:

1) **Acceded to request for change of finished product specifications from BP to USP for products at Sr. No. 1-2.**
2) **Did not accede to request for product at Sr. No. 3 because applied formulation exist in Dietary supplement compendium of USP.**

Furthermore, Registration Board authorized its Chairman to grant approval for change of finished product specification from one pharmacopeia to another pharmacopeia.

43-PRVC.

ii. The request of M/s Bosch Pharmaceuticals (Pvt.) Ltd, Plot No.209, Sector 23, Korangi Industrial Area, Karachi for change of Finished Product Specification of Registered Drug was discussed in 43rd meeting of PRVC. The details are as under;

(Page No.689 – 700/C.) *Dy.No.19534 (R&I) dated: 2-Oct-2019*

Documents as per SOP submitted as under;

a. Fee of Rs.5,000/- for each product (**17-Sep-19**).
b. Copies of initial Registration letter & last renewal status.
c. Relevant Documents for the proposed change.

Sr.#	Reg.No.	Name of Drug(s) with composition	Date of initial reg.& renewal	Proposed Specification	Remarks/Comments
10.	070607	Bofalgan 1g/100ml Infusion Each 100ml contains: Paracetamol……..1gm **(BP Specification)**	18-Aug-11 23-Feb-16	Manufacturer's Specification	The requisite formulation is not available in BP Specification. Hence, correction is needed in finished product specification FPP specification may be granted as per innovator's specification, in the light of decision of RB 267th meeting.

Decision: The Committee referred the request of firm to Registration Board.

Decision: Registration Board deferred the request of M/s Bosch Pharmaceuticals (Pvt.) Ltd, Plot No.209, Sector 23, Korangi Industrial Area, Karachi for submission of data as per decision of Registration Board 267th meeting.

Case No.03: Application for Manufacturing of Already Registered Drug(s) on contract Manufacturing Basis.

In pursuance of DRAP's Circular No.F.76-DRAP/2020 (PE&R) dated 5th May, 2020 regarding **"Priority Approval / Registration of Drugs During the Covid-19 Pandemic"** for priority registration of formulation of Azithromycin.

M/s Martin Dow Marker Limited, 7, Jail Road, Quetta has requested for manufacturing of their following already registered product from M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi on contract manufacturing basis due to non-availability of filling machine at their site. The details of the product are as under;

Sr. No.	Reg. No.	Name of drug with composition	Date of initial registration	Documents submitted
1.	100281	Arzomic Suspension 200mg/5ml Each 5ml contains: Azithromycin dihydrate eq.to Azithromycin……200mg (USP Specification)	19-Dec-19	➢ Application on Form-5 along-with fee of Rs.50,000/- dated 3-Jun-2020. ➢ Copy of initial registration letter. ➢ Copy of agreement b/w contract giver/acceptor (dated 1-Apr-2020). ➢ Copies of DMLs of contract giver/acceptor. ➢ Copy of section approval of proposed manufacturer. ➢ Undertaking.

Decision: Registration Board deferred for registration status of other Dry powder suspension products and justification for contract manufacturing.

Case No.04: Request to allow Campaign Manufacturing of Dexamethasone Injection in Pandemic Situation.

Dy.No.108 (PR-I) dated 27-July-2020

The case of change of title/name of manufacturer from M/s Cirin Pharmaceuticals (Pvt.) Ltd., to M/s ICI Pakistan (Pvt.) Ltd., (site remains the same i.e. 32/2-A, Phase-III, Industrial Estate, Hattar) vide Licensing Division's letter No.F.3-4/92-Lic (Vol-III) (Pt.) dated 18th February, 2020 under DML No.000363 (Formulation) & corrigendum issued on 20-February-2020 for their already registered products; **wherein the following two products were deferred in 38th meeting of PRVC for provision of evidence of section approval Liquid Injectable (Steroid).**

Sr.No.	Reg. No.	Name of Drug with composition	Pack size
1.	060033	Adrenaal Injection Each ml contains: Dexamethasone (as Sodium Phosphate)……....4mg (USP Specifications)	1mlx25's
2.	063093	Adrenaal Injection Each ml contains: Dexamethasone Sodium Phosphate equivalent to Dexamethasone Phosphate.....4mg (USP Specification)	5mlx1's

Firm has not submitted the evidence of section approval of Liquid Injectable (Steroid) but have requested to allow them campaign manufacturing of Dexamethasone Injection as the recent pandemic caused by Covid-19 has led to various studies and trials around the world on different therapeutic solutions against the Coronavirus; one solution is Dexamethasone.

Dexamethasone has been on the World Health Organization Model List of Essential Medicine since 1977. It is a corticosteroid used in a wide range of conditions for its anti-inflammatory and immunosuppressant effects. It was tested in hospitalized patients with Cofid-19 in the United Kingdom's national clinical trial RECOVERY and was found to have benefits for critically ill patients. According to WHO, "for patients on ventilators, the treatment was shown to reduce mortality by about one-third and for patients requiring only oxygen, mortality was cut by about one-fifth". The

health ministry of Japan has also approved the use of the steroid drug dexamethasone for the treatment of novel coronavirus patients.

As a long term solution for manufacturing of Dexamethasone, M/s ICI Pakistan is currently evaluating following two options (either of options will take time to materialize);

i. Construction of Liquid Injectable (Steroid) Section.
ii. Toll Manufacturing arrangement with a third party who have the necessary approved section for manufacturing of Liquid Injectable (Steroid).

Now, the firm has requested that considering the extremely urgent need of Dexamethasone in pandemic, M/s ICI Pakistan may be allowed to manufacture "Corticosteroids" in their approved liquid injectable section on campaign basis by ensuring strict GMP compliance to ensure its free availability for the benefit of patients and medical profession.

Decision: Registration Board did not accede to request of M/s ICI Pakistan (Pvt.) Ltd., 32/2-A, Phase-III, Industrial Estate, Hattar for campaign manufacturing of above-mentioned products as segregated facility is required as decided by Central Licensing Board.

Case No.05: Deferred Cases by 295th Meeting of Registration Board.

i. Change of Contract Manufacturer of Registered Drugs of M/s Bosch Pharmaceuticals (Pvt.) Ltd Karachi from own Plant-I to Plant-II.

Dy.No.4591 (R&I) dated: 16-Mar-20.

M/s Bosch Pharmaceuticals (Pvt.) Ltd, **(Plant-I)** 221, Sector 23, Korangi Industrial Area, Karachi has requested for manufacturing of their following registered products from **Plant-II** i.e. Plot No.209, Sector 23, Korangi Industrial Area, Karachi. The details are as under;

Sr. No.	Name of Drug(s) with Composition & Reg.No.	FPP specification Status	Date of initial Reg. & Renewal Status	Existing Address of Manufacturer	Proposed Address of 01Manufacturer	Documents Submitted & Remarks (if any)
1.	B Tig 50mg Injection Each vial contains: Tigecycline……..50mg **As per Innovator's Specification** (Reg.No.084761)	Formulation exist in USP	18-Sep-17	M/s Bosch Pharmaceuticals (Pvt.) Ltd, **(Plant-I)** Plot No.221, Sector 23, Korangi Industrial Area, Karachi	M/s Bosch Pharmaceuticals (Pvt.) Ltd. **Plant-II:** Plot No.209, Sector 23, Korangi Industrial Area, Karachi	➢ Fee of Rs.50,000/- for each product. ➢ CTD dossier for each product. ➢ Copies of initial registration letters & last renewal status for each product. ➢ Copies of Section approvals. ➢ Contract manufacturing agreement ➢ Undertaking.
2.	Zezot 500mg Injection Each vial contains: Azithromycin (as Dihydrate) ……..…..500mg **Manufacturer's specification** (Reg.No.055017)	Formulation exist in USP	16-Jan-09 28-Nov-16			
3.	Q-Pro 30mg Injection Each vial contains: Lansoprazole……30mg **USP specification** (Reg.No.055018)	Formulation exist in USP	16-Jan-09 28-May-18			
4.	Somezole20mg Injection Each lyophilized vial contains: Esomeprazole (as Sodium) ……..20mg Manufacturer's specification (Reg.No.047446)	Formulation do not exist in any official monograph May be approved with	19-Jan-08 12-Oct-17			

		innovator's specification				
5.	Somezole40mg Injection Each lyophilized vial contains: Esomeprazole (as Sodium) …….40mg Manufacturer's specification Reg.No.045386)	-do-	13-Jun-07 21-Sep-16			
6.	Ticozid 200mg Injection Each vial contains: Teicoplanin……200mg Manufacturer's specification (Reg.No.050514)	-do-	27-Aug-08 5-Apr-18			
7.	Ticozid 400mg Injection Each vial contains: Teicoplanin……400mg Manufacturer's specification (Reg.No.050515)	-do-				
8.	Vinjec 500mg Injection Each vial contains: Vancomycin HCl 525mg eq.to Vincomycin ….500mg (Reg.No.024114)	Formulation exist in USP/BP/JP	7-Oct-02 22-May-17			
9.	Vinjec 1000mg Injection Each vial contains: Vancomycin HCl 1050mg eq.to Vincomycin …….1000mg (Reg.No.024115)	Formulation exist in USP/BP/JP				
10.	Zentro 40mg Injection Each vial contains: Pantoprazole Sodium 44.39mg eq.to Pantoprazole …...40mg Manufacturer's specification (Reg.No.045388)	Formulation do not exist in any official monograph May be approved with innovator's specification	12-Jun-07 21-Sep-16			
11.	Omezole 40mg Injection Each vial contains: Omeprazole (as Sodium) …...40mg (Reg.No.024245)	-do-	7-May-02 21-Sep-16			

Remarks:

1. Validated analytical method of FPP was **not provided**.
2. Stability data (accelerated and real time) of only initial/0 month of FPP was submitted only; however, undertaking was submitted regarding submission of rest of data both accelerated and real time shall be submitted upon completion.
3. Impurity studies were **not performed** by FPP manufacturer (neither of Drug substance nor FPP)
4. Description regarding container closure system/suitability studies was **not provided.**

Decision 295th meeting:
Registration Board deferred the request of firm for provision of above mentioned documents.

Updated status:
Firm has submitted documents in reply of deficiency letter No. F 1-1/2020-PR-1 (Deficiency) dated May 11,2020 as follows:

S.No	Required documents	Submission	Remarks
1.	Drug substance related documents (documents confirming import of API including AD attested commercial invoice etc.) and valid GMP certificate of API manufacturer as required under subsection 1.6.5 of Module 1.	Attested commercial invoices/ CoA are provided	Complied
2.	Analytical procedure and Batch analysis of API by FPP manufacturer as required in Drug Substance part of Module-3	Relevant batch of API has been analyzed by FPP manufacturer	Complied
3.	Validated analytical method should be submitted and specifications should be justified as required under sub section **3.2.P.5.6** (justification of specification) of Module-3.	Validated analytical methods are submitted.	Specifications of formulations available in pharmacopeia need to be justified
4.	Formulation Development and Pharmaceutical Equivalence, comparative study with the innovator product as required in Module-3.	Not applicable	To be submitted
5.	Description of the container closure system, the suitability of the container closure system used for the storage, transportation (shipping) and use of the drug product.	Provided	Complied
6.	Stability Summary and protocol (for both accelerated & long term studies) along with chromatogram, and stability data as required under Drug Product part of Module-3.	Stability data (accelerated and real time) of only initial/0 month is submitted and undertaking provided regarding submission of rest of data both accelerated and real time upon completion.	Stability data for at least three points of time (0,3,6 months) to be provided
7.	Certificate of analysis of drug product by FPP manufacturer	Provided	Complied
8.	Administrative documents such as contract mfg agreement, registration letters/ renewal status	Provided	Complied

Decision: Registration Board deferred the request of M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi for submission of above-mentioned shortcomings.

ii. Request for grant of Contract Manufacturing Permission to M/s Helix Pharma (Pvt.) Ltd, Karachi

M/s Helix Pharma (Pvt.) Ltd, Karachi has requested for grant of permission for contract manufacturing of their following registered products from M/s Opal Laboratories (Pvt.) Ltd, Karachi.

S.#	Reg. No.	Name of Product with Composition	Initial date of registration/ last date of renewal	Demanded FPP specifications	Remarks
1.	028931	Tycef Capsule Each capsule contains: Cefixime……..400mg	13th August 2002 02 August 2017	JP	Firm performed CDP in comparison to Cebosh capsule 400mg in lieu of innovator's product i.e Suprax capsule.
2.	028165	Tycef Paediatric Suspension	10th August 2002 02 August 2017	USP	Comparative study was performed against Vencef

		Each 5ml contains: Cefixime Trihydrate eq. to cefixime …….100mg			100mg suspension by Opal Lab in lieu of innovator's product Suprax 100mg oral suspension
3.	048552	Tycef DS Suspension Each 5ml contains: Cefixime Trihydrate eq. to cefixime…..200mg	20th March 2008 19th March 2018	USP	Comparative study was performed against Vencef DS suspension by Opal Lab in lieu of innovator's product Suprax 200mg oral suspension

The reason provided by firm for proposed change is business feasibility considering the low volumes and turnover with low margins of the said product and excess capacity/manufacturing facility at M/s Opal Laboratories, Karachi.

In this regard, the firm has submitted the following documents;

- **i.** Application on Form-F along-with Fee of Rs.50,000/- each product (dated 15-Oct-19)
- **ii.** Copies of Initial Registration and renewal status.
  Contract manufacturing agreement between M/s Helix Pharma (Pvt.) Ltd, Karachi and M/s Opal Laboratories (Pvt.) Ltd, Karachi dated 24.07.2019
- **iii.** Section approval letter by CLB dated 09-April-2014 (M/s Opal Laboratories (Pvt.) Ltd)
- **iv.** Last GMP inspection report of M/s Opal Laboratories (Pvt.) Ltd, Karachi dated 19th September 2019.

Decision of 293rd meeting: Registration Board deferred the request of firm for status of cephalosporin section (capsule/dry suspension) of M/s Helix Pharma (Pvt.) Ltd, Karachi.

Updated Submission:

The firm has submitted clarification regarding Capsule/dry suspension cephalosporin section which was approved in 13th June 2002 vide letter No. F.2-20/84-Lic Vol-II (M-192). Firm has initiated a major renovation/up gradation project, revised lay out plan has been approved by Licensing division dated 22nd July, 2019 vide letter No. F.2-20/1984-Lic (Vol-IV). Considering that current renovation/up gradation project firm's business viability of cephalosporin area complemented with available excess capacity at manufacturing facility of M/s Opal Laboratories, Karachi for interim period of 03 years.

Decision 295th meeting: Registration Board deferred the request of M/s Helix Pharma (Pvt.) Ltd, Karachi for manufacturing of their above mentioned products on contract manufacturing basis from M/s Opal Laboratories (Pvt.) Ltd, Karachi for submission of renovation plan along-with clear timelines and undertaking**.**

Updated status:

The firm has submitted renovation plan along-with clear time lines and undertaking that approved renovation plan will be completed within a period of 12 to 16 months after obtaining DRAP approval for contract manufacturing of Tycef range of products. The time lines submitted as follows:

Phase 1: Renovation of general packaging area (tablets and capsules) will be completed by Dec-2020
Phase II: Renovation of blistering, coating &encapsulation will be completed by May 2021.
Phase III: Renovation of Dry Suspension, blending, granulation and packaging will be completed by November 2021
Phase IV: Renovation of liquid manufacturing, filling and packing will be completed by March 2022.
Phase V: Renovation of oral cephalosporin (capsule and dry powder suspension) will be completed by Feb,2022

Form 5F of firm was reassessed in the light of guidelines regarding implementation of CTD discussed in 293rd meeting of Registration Board. Following documents were submitted by the firm as per checklist approved by Registration Board in 293rd meeting:

Documents required	Status	Remarks
1. Form 5-F:	Complied	
2. Requisite fee:	Complied	
3. Valid DML / DSL:	Complied	

4. Evidence of GMP compliance of relevant section:	Complied	
5. Evidence of approval status in RRA:	Complied	
6. QOS (Quality Overall Summary) as per WHO QOS-PD Tem-plate:	Complied	
For Module-3, in Drug Substance part:		
3.2.S.2.1: Manufacturer(s) site address	Complied	
3.2.S.4.4: Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:	Complied	
3.2.S.7: Stability data of 3 batches at accelerated and real time conditions:	Complied	Data submitted as per Zone-IVA condition
For Module-3, in Drug Product part:		
3.2.P.2.2.1: Product development, description of dosage form, Pharmaceutical Equivalence through Comparative Dissolution Profile (where applicable)	Complied	
3.2.P.3.5: Process validation:	Complied	
3.2.P.5.1: Specifications of drug product:	Complied	
3.2.P.5.3: Validation / verification of analytical procedures summary / reports:	Complied	
3.2.P.8.3: Stability data:	Complied	Stability data submitted along with supporting documents like chromatograms, Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC software 21CFR & audit trail reports on product testing submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers submitted

Decision: Registration Board acceded to request of M/s Helix Pharma (Pvt.) Ltd, Karachi for contract manufacturing of their above mentioned registered products from M/s Opal Laboratories (Pvt.) Ltd, Karachi for the period of 16 months as per Rule 20A(1)(c) of Drugs (Licensing, Registering and Advertising) Rules, 1976.

The firm will submit quarterly progress report on the activities undertaken under the aforementioned submitted plan for appraisal of Registration Board. In case of non-compliance for above time lines, Registration Board will be informed accordingly.

iii. Change of Primary Packaging.

Dy.No 3960 (R&I) dated: 9-Mar-20 & Dy.No. 6795 (R&I) dated: 10-Apr-20

M/s. Pharmatec Pakistan (Pvt.) Ltd; Karachi requested for change in primary packaging material of following products details are as under:

Sr.#	Reg. No.	Name of Product with composition	Existing Packaging	Proposed Packaging	Remarks
1.	019762	Reltus DM liquid Each 5ml contains: Dextromethorphan HBr ……. 10mg Pseudoephedrine HCl…….30mg Chlorphineramine Maleate……2mg	Amber glass bottle Alu cap 25mm with 1.8 WAD	Amber PET bottle Plastic cap PET bottle 60/120ml	RRA approval status not confirmed

2.	017570	Reltus cough expectorant Ammonium Chloride ……. 100mg Phenylephrine HCl…….5mg Chlorphineramine Maleate……2mg	Amber glass bottle Alu cap 25mm with 1.8 WAD	Amber PET bottle Plastic cap PET bottle 60/120ml	RRA approval status not confirmed

The stability data submitted by the firm **(accelerated=6months & Long-term= 6months).**

Details of Submission:

Firm has submitted the following documents as per SOP (approved in 283rd meeting).

Sr.#	Documents Required (as per SOP M-283)	Information Provided
1.	Application with required fee as per relevant SRO.	Date of applications 10-April-2020; Rs.5,000/- for each product.
2.	Copy of registration letter and last renewal status	Reg. No. 019762 (dated 07-08-1996) Last renewal dated 27.05.2015 (Rs.10,000/-) Reg. No. 017570 (dated 27-06-1995) Last renewal dated 27.05.2015 (Rs.10,000/-)
3.	Justification of proposed change including data on the suitability of the container-closure system (e.g. extractable/ leachable testing (where applicable), permeation testing, light transmission) demonstrating equivalent or superior protection compared to the current packaging system. For changes to functional packaging related to container closure (e.g. MDIs etc.), data to demonstrate the functioning of the new packaging	Data regarding suitability of proposed packaging material is provided from supplier i.e. Novatex Ltd. Following tests are performed: a) Leachable/extractable test as prescribed by FDA b) heavy metals determination
4.	If the container closure system of applied formulation is different from that of the reference product, manufacturer will place first three lab scale batches or developmental scale batches as set by Registration Board in 276th meeting, at 3 months of accelerated and 3months of real time studies for compatibility of applied formulation with container closure system as directed by Pharmacopeia of Reference Regulatory Authorities. Registration Board shall be informed immediately and along with market withdrawal in case of any significant change about result of stability studies	**Accelerated studies** (Temp 40◦C±2◦C/ RH 75%±5%) Interval: 0,3,6 months **Long term studies** (Temp 30◦C±2◦C /RH 65%±5%) **Interval**: 0,3,6 months **Reltus DM liquid** **Testing parameters**: description, ph, assay (dextromethorphan, pseudoephedrine, chlorphineramine maleate, microbiological tests (total aerobic count, yeast and mold count, gas forming organism. Batch No: 0383, 0267, 0381 Type of container: Amber PET bottle with plastic cap **Reltus cough expectorant** **Testing parameters**: description, ph, assay (ammonium chloride, phenylephrine, chlorphineramine maleate, microbiological tests (total aerobic count, yeast and mold count, gas forming organism. Batch No: J67BH, J67B1,189PE Type of container: Amber PET bottle with plastic cap **Batch size:** 6000 bottles **Sample size**: 15 bottles for real time studies, 5 bottles for accelerated studies.
5.	Shelf life of drug product supported with justification.	Provided
6.	Existing and proposed container closure system with differences (e.g. description, materials of construction of primary packaging components, specifications, if appropriate) highlighted in tabular form.	Comparison between Amber glass bottle and Amber PET bottle is provided in tabulated form.

7.	If the proposed change requires change in manufacturing section/ facility, then a new registration application with prescribed fee shall be submitted.	Not applicable
8.	An Undertaking that: • To perform stress studies. • In case of any quality complaint/OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. • Provided information is true & correct.	provided

A study report for container closure system performed by Smithers lab for Novatex Ltd. as follow:

Sr.#	Tests performed
1.	Specific migration of mono and diethylene glycol, terephtalic acid and antimony by total immersion into simulants.
2.	FDA extraction test as specified inUS FDA code of federal regulations CFR21
3.	Determination of levels of Pd, Cd, chromium and mercury

Certificate of Analysis by packaging material supplier i.e. Auvitronics Limited submitted. Auvitronics Limited buy raw material from Novatex Ltd.

Remarks:

Shortcomings	Reltus Cough Expectorant (Reg.No.017570)	➢ Validated analytical testing method/pharmacopeial reference not provided
	Reltus DM liquid (Reg.No.019762)	➢ Related substances were not tested ➢ Validated analytical testing method /pharmacopeial reference not provided ➢ Chromatograms are not submitted ➢ Certificate of analysis for each point of time is not provided ➢ Stability protocol not provided

Decision 39-PRVC:

The Chairman Registration Board referred the case to Registration Board after submission of shortcomings by the firm as mentioned above.

Updated Submission:

The firm has now submitted validated analytical testing method for product Reltus Cough Expectorant (Reg.No.017570); however, documents submitted for product Reltus DM liquid (Reg.No.019762) were not satisfactory.

Decision 295th meeting:

Registration Board deferred the request of firm for confirmation of primary packaging material of same/similar formulation approved in any Reference Regulatory Authorities.

Updated Status:

1) References regarding availability of similar formulations in proposed container closure system are provided by the firm as follows:
   a) **Chlorpheniramine Maleate** containing formulation Boots children's allergy relief antihistamine syrup (MHRA approved, UK) available in PET bottle
   b) **Phenylephrine HCl** containing formulation Covonia cold & flu formula oral solution (MHRA approved, UK) available in PET bottle.
   c) **Ammonium Chloride** containing formulation Pimacolin Rasa Apel plus syrup (Indonesia, ASEAN country) available in PET bottle. (https://www.pengobatan.org/indonesia-id/pimacolin-rasa-apel-plus-syrup)

2) Firm has submitted documents regarding **Reltus cough expectorant** (Reg No. 017570) in dated 11.08.2020 as follows:

Documents submitted	Status	Remarks

Real time stability data for the period of 9 months along with raw data sheets and chromatograms, as per zone IV-A condition	Submitted	Previously firm submitted 6 months stability data for accelerated and 6 months for real time studies.
Validated analytical method	Submitted	Complied
Justification of shelf life	Based on stability data , the shelf life is proposed to be 2 years	Complied
Justification of proposed change (glass to PET)	The stability data has been found satisfactory in proposed container closure system.	Complied
Certificate of Analysis of packaging material from supplier Auvitronics Limited submitted	Submitted	Complied
Technical report (food contact compliance) from smithers prepared for Novatex Ltd.	Tests performed included: • Specific migration of mono and diethylene glycol, terephtalic acid and antimony by total immersion into simulants. • FDA extraction test as specified in US FDA code of federal regulations CFR21. • Determination of levels of Pd, Cd, chromium and mercury	Tests for pharmaceutical grade packaging material need to be performed as per USP General chapter <661> container. Following tests to be performed for PET bottle: • Multiple internal reflectance • Thermal analysis • Light transmission • Water vapor permeation • Colorant extraction • Heavy metals

Decision: Registration Board deferred the request of M/s. Pharmatec Pakistan (Pvt.) Ltd; Karachi for providing data regarding performance of tests of packaging material as per USP General chapter <661> container or any other official monograph of any reference regulatory authority for confirmation of packaging material to be used is of pharmaceutical grade or not.

Case No.01: Registration of Drug(s) of M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area Karachi For Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided **Approval of relevant section i.e Liquid injection (steroidal hormone) not verified.**
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on inspection dated 30.12.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Perluton Injection 500mg/2ml Each 2ml contains: Hydroxyprogesterone caproate……500mg	Me too status/ RRA status not available Purchase order from Kenya **FDA approved formulation as 250mg/ml**	Dy. No1061/ 2020-PE&R-(EFD) 27-08-2020. Rs.20000/- dated 07-07-2020 Rs.30000/- dated 23-07-2020

Decision: Registration Board deferred above mentioned product of M/s Geofman Pharmaceuticals, 20/23, Korangi Industrial Area Karachi for confirmation of injection hormone (steroid) section.

Case No.02: Registration of Drug (s) of M/s BF Biosciences Ltd. 5-Km, Sunder Raiwind Road, Raiwind Lahore For Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Parenterals (Campaign Manufacturing vide decision of Drug Appellate Board (Letter No.F.1-3/2018-AB (M-15) on 04.02.2019) from DML renewal inspection report dated 22.08.2019
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from DML renewal inspection report dated 22.08.2019

Undertakings that the applied product is exclusively for export purpose & proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Remidia Lyophilized Powder for infusion Each vial contains: Remdesivir…….100mg	USFDA Emergency use authorization	Dy. No1068/ 2020-PE&R-(EFD) 27-08-2020. Rs.50000/- dated 12-06-2020
2	Remidia Solution for Infusion 20ml Each ml contains: Remdesivir…….5mg	USFDA Emergency use authorization	Dy. No1069/ 2020-PE&R-(EFD) 27-08-2020. Rs.50000/- dated 12-06-2020

Decision: **Registration Board approved above mentioned products of M/s BF Biosciences Ltd. 5-Km, Sunder Raiwind Road, Raiwind Lahore for export registration. Since applied formulation is approved for Emergency Use Authorization by RRAs (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Case No. 03: Registration of Drug(s) of M/s Wnsfeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Renewal of DML inspection dated 18-1-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Renewal of DML inspection dated 18-1-2020
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Atta-Pulgite 3gm Sachet Each sachet contains: Attapulgite……..3gm	Me too status/ RRA status not available Purchase order from Burundi	Dy.No.2077 /19-EFD (PE&R) dated 31-08-2020 Rs.50000/- dated 07-08-2020
2.	Aceclofenac plus Tablet Each extended release film coated tablet contains: Aceclofenac……100mg Chlorzoxazone……375mg Paracetamol…….500mg	Me too status/ RRA status not available Purchase order from Burundi	Dy.No.2078 /19-EFD (PE&R) dated 31-08-2020 Rs.50000/- dated 24-06-2020

3.	Atta-Pulgite 1gm Sachet Each sachet contains: Attapulgite……..1g	Me too status/ RRA status not available Purchase order from Burundi	Dy.No.2077 /19-EFD (PE&R) dated 31-08-2020 Rs.50000/- dated 24-06-2020

Decision: **Registration Board approved above mentioned products of M/s Wnsfeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Case No. 04: Registration of Drug(s) of M/s EG Pharmaceuticals for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5 submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F 1-26/2004-Lic dated 29th August, 2012 DML renewal inspection dated 13.02.2019
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from DML renewal inspection dated 13.02.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Erosat Tablet 20mg Each enteric coated tablet contains: Serratiopeptidase……20mg	Danzen 20mg tablet by Helix pharmaceutical	Dy.No.2079 /-EFD (PE&R) dated 31-08-2020 Rs.20,000/- dated 11-02-2020
2.	Erosat Tablet 10mg Each enteric coated tablet contains: Serratiopeptidase……10mg	Danzen 10mg tablet by Helix pharmaceutical	Dy.No.2080 /-EFD (PE&R) dated 31-08-2020 Rs.20,000/- dated 11-02-2020

Decision: **Registration Board approved above mentioned products of M/s EG Pharmaceuticals 13-A, Industrial triangle, Kahuta Road, Islamabad for export registration.**

Case No. 05: Registration of Drug(s) of M/s Atco Laboratories Limited, B-18, S.I.T.E Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5 submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided

	Approval of relevant section verified from Renewal of DML Inspection dated 28-02-2017.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 09-07-2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	D-All Injection Each ml contains: Cholecalciferol (Vitamin D3)……..7.5mg (300,000IU)	Me too/RRA status not available Purchase order from Kenya	Dy.No.2080 /19-EFD (PE&R) dated 31-08-2020 Rs.50,000/- dated 17-08-2020

Decision: **Registration Board approved above mentioned products of M/s Atco Laboratories Limited, B-18, S.I.T.E Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Case No. 06: Registration of Drug(s) of M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5 submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F.1-11/92-Lic(Vol-III) dated 09-3-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on inspection dated 17& 18.01.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1	Codesvir 100mg Injection Each 20ml vial contains: Remdesivir……..100mg	Redzi solution for infusion by Wnsfeild	Dy.No.1082 /19-EFD (PE&R) dated 27-08-2020 Rs.20,000/- dated 28-07-2020

Decision: **Registration Board approved above mentioned product of M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for export registration. Since applied formulation is approved for Emergency Use Authorization by RRAs (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product**

Case No. 07: Registration of Drug(s) of M/s Medisure Laboratories (Pvt) Ltd. A-115, S.I.T.E Super Highway Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F.2-2/2001-Lic (Vol-I) dt: 19-07-2012
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP Inspection dated 19.07.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1	Parbisure 5ml Injection Each 5ml ampoule No.1 contains: Thiamine hydrochloride……..250mg Riboflavin (as phosphate sodium)…4mg Pyridoxine hydrochloride…….50mg Each 5ml ampoule No. 2 contains: Ascorbic acid……500mg Nicotinamide…….160mg Glucose (as monohydrate)…1000mg	Me too status/ RRA status not available Purchase order from Myanmar	Dy.No.2081 /20-EFD (PE&R) dated 27-08-2020 Rs.20,000/- dated 29-09-2019 Rs.30,000/- dated 12-08-2020

Decision: Registration Board approved above mentioned product of M/s Medisure Laboratories (Pvt) Ltd. A-115, S.I.T.E Super Highway Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 08: Registration of Drug(s) of M/s Rakaposhi (Pvt) Ltd. 97-K, Hayatabad Industrial Estate Peshawar for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F.3-6/94-Lic (Vol-II) dated 05-08-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP Inspection dated 19.09.2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1	Tablet RN-DOL 200mg Each tablet contain: Tramadol HCI…….200mg	Me too status/ RRA status not available Purchase order from Afghanistan	Dy.No.2063 /20-EFD (PE&R) dated 27-08-2020 Rs.50,000/- dated 19-08-2020

Decision: Registration Board approved above mentioned product of M/s Rakaposhi (Pvt) Ltd. 97-K, Hayatabad Industrial Estate Peshawar for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 09: Registration of Drug(s) of M/s Novamed Pharmaceuticals 28-KM, Ferozepur Road Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F.6-1/2013-Lic (M-232) date 29-8-2013
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on Inspection dated 22.01.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Mexihelp Injection 5ml Each ml contains: Ethylmethyl hydroxy pyridine succinate……..50mg	Me too status/ RRA status not available Purchase order from Kyrgyzstan	Dy.No.2064 /20-EFD (PE&R) dated 27-08-2020 Rs.50,000/- dated 19-06-2020

Decision: Registration Board deferred above mentioned product of M/s Novamed Pharmaceuticals 28-KM, Ferozepur Road Lahore for regulatory approval status in importing country and proposed indications with justification. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 10: Registration of Drug(s) of M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F.1-51/2004-Lic dated 07-02-2014

GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on Inspection dated 08.11.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Cal-Max syrup Each 5ml contains: Calcium Lactate Gluconate……..40mg Vitamin A……1200I.U Vitamin D3…….100 I.U Vitamin B1 ……..……1mg Vitamin B2…… …..1mg Vitamin B6 ……..……...0.5mg Nicotinamide……5mg Dexpanthenol……..2mg Vitamin C…….50mg Vitamin E……1mg	Me too status/ RRA status not available Purchase order from Afghanistan	Dy.No.2065 /20-EFD (PE&R) dated 27-08-2020 Rs.20,000/- dated 10-01-2018 Rs.30,000/- dated 12-03-2020 **Remarks:** **The individual quantities of ingredients found below RDA.**

Decision: Registration Board deferred above mentioned product of M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road Lahore for verification of formulation whether below/equal or above RDA. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 11: Registration of Drug(s) of M/s Zaynoon Pharmaceuticals (Pvt) Ltd. 27-28-B, Industrial Estate, Hayatabad, Peshawar for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from CLB letter No. F. 3-2/93-Lic dated 13-04-2017
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on Inspection dated 11.01.2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1	Zayfed-P Syrup Each 5ml contains: Triprolidine……1.25mg Pseudoephedrine……30mg Paracetamol……80mg	Actifed-P Syrup by GSK	Dy.No.2096 /20-EFD (PE&R) dated 31-08-2020 Rs.20,000/- dated 31-08-2020

Decision: **Registration Board approved above mentioned product of M/s Zaynoon Pharmaceuticals (Pvt) Ltd. 27-28-B, Industrial Estate, Hayatabad, Peshawar for export registration.**

Referred Cases of 42nd PRVC

Case No. 12: Registration of Drug(s) of M/s Welwrd Pharmaceuticals, Plot No.3, Block A, Phase I-II Industrial Estate Hattar for Export Purpose Only

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 1386-1428 /C)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page.1434/C) Approval of relevant section verified from Licensing Section letter F.No.2-20/85-Lic (vol-V) dated 27.04.2020 (Page.1435 /C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based on inspection report dated 23-07-2019 (Pages. 1436/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Page 1429-1433/C)

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Remdis 5mg/ml Injection Each vial (20ml) contains: Remdesivir……..100mg	Redzi solution for infusion by Wnsfeild	Dy. No.1800/2020-PE&R-(EFD) 26.6.2020. Rs.20000/- date 22.06.2020

Decision: The Committee referred above mentioned product to Registration Board.

Decision: **Registration Board approved above mentioned product of M/s Welwrd Pharmaceuticals, Plot No.3, Block A, Phase I-II Industrial Estate Hattar for export registration. Since applied formulation is approved for Emergency Use Authorization by RRAs (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Case No. 13: Registration of Drug(s) of M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small industrial Estate, Taxila for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 747-758/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML (Pages. 761/C) Approval of relevant section verified from CLB letter No. page. 762/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 01-03-2019 (Page. 763/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 759-760/C)

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV

1.	Remvir for Injection 100mg Lyophilized powder Each vial contains: Remdesivir Lyophilized sterile powder……..100mg	USFDA Emergency Use Authorization	Dy. No.1715/2020-PE&R-(EFD) 02.06.2020. Rs.50000/- dated 19.05.2020
2	Remvir 5mg/ml injection Each 20ml vial contains: Remdesivir……100mg	USFDA Emergency Use Authorization	Dy. No.1716/2020-PE&R-(EFD) 02.06.2020. Rs.50000/- dated 19.05.2020

Decision: The Committee referred above mentioned products to Registration Board

Decision: Registration Board deferred above mentioned products of M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small industrial Estate, Taxila for availability of concerned sections i.e Liquid injection (vial) and Dry powder injection (lyophilized) vial.

Case No.14: Registration of Drug(s) of M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Area Hattar for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 825-829/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML (Page. 882/C) Approval of relevant section verified from Licensing Board Letter No.F.3-6/2007-Lic (Vol-I) dated 3.4.2015 Page. 833/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 20-02-2019 (834-836/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Page. 831/C)

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Remida 5mg/ml Injection Each vial contains: Remdesivir……..100mg	USFDA Emergency Use Authorization	Dy. No.1718/2020-PE&R-(EFD) 02.06.2020. Rs.50000/- dated 21.05.2020

Decision: The Committee referred above mentioned product to Registration Board.

Decision: Registration Board deferred above mentioned product of M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Area Hattar for availability of concerned sections i.e Liquid injection (vial).

Deferred case of 42nd PRVC:

Case No. 15: Registration of Drug(s) of M/s Medisure Laboratories Pakistan (Pvt) Ltd. A-115, S.I.T.E. II, Super Highway Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages.1108-1125/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided(Page.1131/C) Approval of relevant section verified from Licensing Section letter F.No.2-2/2001-Lic (Vol-I) & (Vol-II) dated 12.02.2013 dated 197.2012 & 12.02.2013 (Page. 1125-1127/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 19-07-2019 (Pages.538-539 /C).
Undertakings that the applied product is exclusively for export purpose and the proposed	Provided (Page.1108-1125/C)

names/ label/ colour do not resemble with already registered brands in importing country.	

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Nero-B6 100mg/ml injection Each ml contains: Pyridoxine Hydrochloride……100mg	Me too status not confirmed	Dy. No.1730/2020-PE&R-(EFD) 09.06.2020. Rs.20000/- dated 17.03.2020

Decision 42nd PRVC:The Committee deferred above mentioned product for confirmation of me too status. Updated status: Now the firm has provided Purchase order from China and differential fee of Rs. 30000/- vide slip No.2029105 dated 10/08/2020. Formulation also found approved in USFDA.

Decision: **Registration Board approved above mentioned product of M/s Medisure Laboratories Pakistan (Pvt) Ltd. A-115, S.I.T.E. II, Super Highway Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Referred cases of 44th PRVC

Case No.16: **Registration of Drug (s) of M/s NabiQasim Industries Private Limited 17/24, Korangi Industrial Area, Karachi for Export Purpose Only.**

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D & Form 5; (Pages 764-839/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-846/C). Approval of relevant section verified from Licensing section letter No.F.2-20/85-Lic (Vol-III) (M-227) dated 20.6.2011 (Pages.847/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 23.11.16 (Pages. 848-849/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages.840-845/C)

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**REMIVID 100mg Injection Lyophilized powder** Each vial contains: Remdesivir Lyophilized powder…….100mg	USFDA Emergency Use Authorization	Dy. No.1856/2020-PE&R-(EFD) 21.07.2020. Rs.50,000/- dated 29.06.2020

Decision 44th PRVC: The Committee referred the product to Registration Board.

Decision: **Registration Board approved above mentioned product of M/s NabiQasim Industries Private Limited 17/24, Korangi Industrial Area, Karachi for export registration. Since applied formulation is approved for Emergency Use Authorization by RRAs (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product**

Case No.17: Registration of Drug (s) of M/s Welmark Pharmaceuticals Plot No. 122 Block D, Phase V, Industrial Estate, Hattar for Export Purpose Only (Contract Manufacturing by Welwrd Pharmaceuticals Hattar.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D; (Pages 1231-1237/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-1241-1242/C). Approval of relevant section verified from Licensing section letter No. 3-7/2004 dated 09.6.2016 (Pages.1243/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from routine GMP inspection dated 12.11.18 (Pages.1244-1248/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages.1238/C)
Contract Manufacturing Documents	Provided (Pages.1239-1240/C)

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
2.	**REMEDI 5mg/ml Injection** Each vial (20ml) contains: Remdesivir ……100mg	USFDA Emergency Use Authorization	Dy. No.1801/2020-PE&R-(EFD) 26.06.2020. Rs.50,000/- dated 05.06.2020

Decision: The Committee referred the product to Registration Board.

Decision: Registration Board approved above mentioned product of M/s Welmark Pharmaceuticals Plot No. 122 Block D, Phase V, Industrial Estate, Hattar on contract manufacturing by Welwrd Pharmaceuticals Hattar (for period of five years) for export registration. Since applied formulation is approved for Emergency Use Authorization by RRAs (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product

Case No.18: Registration of Drug (s) of M/s Maxitech Pharma (Pvt.) Ltd. Plot No. E-178 S.I.T.E. Phase-II Super Highway, Karachi. for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages 1273-1282/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-1285). Approval of relevant section verified from Licensing section letter No. 2-12/2012-Lic dated 25.11.2011 & 3.12.2018 (Pages.1287/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from inspection dated 04.10.19 (Pages. 1288-1291/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages.1283-1284/C)

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**SILIMAR 200mg Tablet** Each film coated tablet contains: Silymarin …….200mg	**Silliver 200mg** Abbott Laboratories	Dy. No.1926/2020-PE&R-(EFD) 29.07.2020. Rs.20,000/- dated 22.07.2020

Decision 44th PRVC: The Committee referred the product to Registration Board

Decision: Registration Board deferred above mentioned product for further deliberation.

Deferred case of 295th meeting of Registration Board

Case No.19: Registration of Drug(s) of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat for Export Purpose Only (for veterinary use)

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML renewed dated 19.06.2013 (Approval of relevant sections verified from Licensing Division letters No. F.1-4/2007-Lic-(Vol-I) dated 09.07.2015. **Veterinary liquid injection vial**
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 26.10.2018 rated as satisfactory
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Formicgen 60% Solution Each ml contains: Formic acid…….600mg	Me too status /RRA approval status not available Purchase order from Afghanistan	Dy. No.666/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019
2.	Bekchlogen 5% Solution Each ml contains: Benzalkonium Chloride……..50mg	Me too status /RRA approval status not available Purchase order from Afghanistan	Dy. No.667/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019

Decision of 291st meeting of Registration Board:

Registration Board deferred above mentioned products of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat for evidence of approval of applied formulations in importing country.

Now, the firm has clarified that applied formulations Formicgen 60% Solution and Bekchlogen 5% Solution intended to be used as an insecticide to kill bee mites. Either used as Fumigant or applied directly on bee hives/bee path.

Applied formulation is available in China for the same purpose.

Decision 293rd meeting:

Registration Board deferred the request for clarification from the firm about indications of above mentioned products.

Now, firm has submitted detail regarding indication of above mentioned formulation as under:

Benzalkonium Chloride is primarily used as a preservative and antimicrobial agent. It works by killing microorganisms and inhibiting their further growth.

Formic acid is commonly used as preservative and antibacterial agent in livestock feed. It is widely used to preserve winter feed for cattle.

Decision 295th meeting:
Registration Board deferred above mentioned products for further deliberation.

Decision: Registration Board deliberated that as per available data, above mentioned products are not registered as drugs in any part of world. However, if applicant still want to have export registration then any document of concerned regulatory authority may be shared for consideration by the Board.

Deferred case of 293rd Registration Board meeting

Case No.20: Registration of Drug (s) of M/s Star Labs (Pvt) Ltd. Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from DML copy
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 12.11.18
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Cargin Injection (I.V) Each ml contains: L Arginine HCI……42.0mg L-Carnitine… ……...20.0mg	Me too status and RRA reference not confirmed	Rs.50000/- dated 06.05.2019

The firm has submitted purchase order from Ajman UAE (importing country).

Decision 293rd meeting**:** Registration Board deferred above mentioned product of M/s Star Labs (Pvt)Ltd. Lahore for regulatory approval status in importing country and proposed indications with justification.

Updated status:

Now the firm has submitted purchase order from Uzbekistan and photos of unit carton of product LEVARGIN as evidence of approval of applied formulation in importing country. Further, more firm submitted references regarding proposed indications of applied formulation i.e Ischemic heart disease and acute myocardial infraction (https://www.uf.ua/en/cardiologist/results-of-the-study-of-efficacy-and-tolerance-of-tivor-l-sup-sup-in-combination-treatment-of-patients-with-non-st-elevation-acute-coronary-syndrome-and-unstable-angina/ accessed on 02 Sep,2020)

Decision: Registration Board approved above mentioned product of M/s Star Labs (Pvt) Ltd 23 Km Multan road, Lahore for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Deferred Case of 294th Meeting of Registration Board:

Case No. 21 Registration of Drug(s) of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E Super Highway, Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from DML renewal inspection report dated 30.12.2014.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 18.10.2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Oragel adult 16+ Gel Each 100gm contains: Choline Salicylate ……. 8.7% w/w Cetalkonium Chloride …..0.01% w/w Lidocaine……...0.2 %w/w	Me too status/ RRA status not available Purchase order from Kenya	Dy. No1413/ 2020-PE&R-(EFD) 06-04-2020. Rs.50000/- dated 18-03-2020

Decision of 294th Meeting: Registration Board deferred for further deliberation.

Decision: Registration Board deferred above mentioned product of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E Super Highway, Karachi for regulatory approval status in importing country and proposed indications with justification.

Case No. 01: M/s. CCL Pharmaceuticals Pvt. Limited, Lahore

The request of M/s. **CCL Pharmaceuticals Pvt. Limited, Lahore** for change in brand name of already registered products of their following registered product(s) was referred to the Registration Board in 43rd PRVC meeting.

Sr. #	Registration No.	Name of Brand Name with composition	Proposed Brand Names	Date of Initial Reg. & Date Renewal Application	Justification / Remarks/ Deficiency (if any)
1.	025410	**Oadmax Tablet** Each Tablet contains:- Vitamin A (as acetate and betacarotene)……...10mg Vitamin B1 …….1.5mg Niacin.....20mg Vitamin E …….....30mg Folic Acid……..…….0.4mg Biotin…….....30mcg Iron.....18mg Phosphorus ……...100mg Magnesium ……..….100mg Zinc ……..……..15mg Selenium ……..….10mcg Manganese…….2.5mg Chloride ……..…34mg Vitamin C ……..60mg Vitamin B2 ……...…1.7mg Vitamin D……..….10mcg Vitamin B6.....2mg Vitamin B12.....6mcg Pantothenic acid ….…10mg Calcium …….130mg Iodine ……..….....150mcg Copper ……..2mg Chromium……10mcg Molybdenum .……10mcg Potassium ……...37.5mg	**Once A Day Max**	17-11-1999 Change of brand name dated 31-01-2000; 08-07-2019 & 11-06-2019 Due: 14-08-2015 Submitted: 04-08-2015 **Renewal is ok**	Fee Rs. 20,000/- deposited for both product dated 13-03-2020 **Justification** The firm has submitted that **OAD** brand name is already enlisted for our Health & OTC product and requested to revert back our earlier registered brand name
2.	025411	**Oad-AX Tablet** Each tablet contains:- Vitamin A…….10mg Vitamin C……....500mg Vitamin E….……125mg Zinc ……..…….7.5mg Copper ……..1.0mg Selenium ……15.0mcg Manganese…….…..…..1.5mg	**Once A Day AX**		

Decision: The registration Board deferred the request of firm for change in brand name as matter has already been referred to DRAP's Authority.

Case No. 02: Resemblance/Similarity of brand name Mefnac of M/s Efroze Chemical Industries with Mefnax of M/s Qintar Pharmaceuticals, Sargodha.

M/s. Efroze Chemical Industries, Karachi has informed that the brand name of their registered product Mefnac tablets (Reg. No. 004481) and Mefnac DS tablets (Reg. No. 011270) has close resemblance/similarity with the brand name of product of M/s. Qintar Pharmaceuticals, Sargodha. The brief facts of this matter are as follows:

1. Registration of our Mefnac tablets was granted to Efroze Chemical Industries by the Ministry of Health much earlier than Mefnax of Qintar Pharmaceuticals as evident from the registration numbers

    - MEFNAC TABLETS (EFROZE) -- Registration No. 004481
    - MEFNAX TABLETS (QINTAR) -- Registration No. 030647

    - MEFNAC DS TABLETS (EFROZE) -- Registration No. 011270
    - MEFNAX DS TABLETS (QINTAR) -- Registration No. 030648

2. Mefnac range of products (Efroze) has been in the market since **October 1985** while Mefnax range was launched in **April 2004** i.e. after a lapse of more than 18 years.

Now, please refer to our letter No. NIL dated December 29, 2003 and subsequent reminders on the above subject:

1. No. NIL dated April 08, 2004
2. No. 786/ECI/050627-02 dated June 27, 2005
3. No. 786/ECI/050927-01 dated September 27, 2005
4. No. 786/ECI/051128-01 dated November 28, 2005
5. No. 786/ECI/070208-01 dated February 08, 2007

In response to our letters, the Ministry of Health advised M/s Qintar Pharmaceuticals to change the brand name of their product through letters

1. No. F.21-3/2005-Reg-II (North) dated December 27, 2005 &
2. No. F.21-3/2005-Reg-II (North) dated January 16, 2006 both issued by Mr. Ghazanfar Ali Khan, Assistant Drugs Controller Reg-II,
3. No. F.21-3/2005-Reg-II (North) dated November 1st, 2006 issued by M. Akhtar Abbas Khan, DDC (Reg II, North)

M/s Qintar Pharmaceuticals did not take any action to comply with the advice of the Ministry of Health per the above letters.

Due to non-compliance of the Ministry's letters by Qintar Pharmaceuticals the case was placed and discussed in the **200th meeting** of Registration Board held on September 05, 2006, and the decision was as under:

> *"The Board decided to **issue show cause notice** to M/s Qintar Pharmaceuticals Sargodha"*

Subsequently, M/s Qintar Pharmaceuticals was advised through Ministry's letter No. F.21-3/2005-Reg-II (North) dated November 01, 2006, to change the brand name of their product namely Mefnax **within a fortnight** because of similarity in brand name with Efroze's already registered and marketed product MEFNAC TABLETS.

M/s Qintar Pharmaceuticals was asked and warned by Ministry's letter no. F.13-3/2005-Reg-II (North)(M-206) dated June 06, 2007 to appear for **personal hearing** before the Board on 09-06-2007 at 10.00 am in the committee room of Ministry of Health before taking final decision, but by continuously violating the norms **no one** as a representative from M/s Qintar Pharmaceuticals appeared for the personal hearing regarding this serious issue.

Moreover, the registration board in its **204th meeting** decided to call the M/s Qintar Pharmaceuticals, Sargodha for the personal hearing. The firm called for personal hearing Mr. Azhar Hussain of M/s Qintar Pharmaceuticals, Sargodha appeared before the boards and presented the case, and the decision published in DRB **209th** dated 31st August – 1st September 2007.

> *"M/s Qintar Pharmaceuticals was **agreed to change their brand name**. The firm was advised to propose new brand name within two weeks".*

But still, Mefnax Tablet is available in market with same brand name which is pure noncompliance of DRAP decision. On the basis of above true and accurate facts we, Efroze Chemical Industries are confident to say that the product MEFNAX of M/s Qintar Pharmaceuticals should be **deregistered,** as the Ministry has already issued three letters advising to change the brand name and finally a personal hearing with Mr. Azhar Hussain of M/s Qintar Pharmaceuticals, Sargodha in which they agreed to change their brand name.

Decision: **Keeping in view the background of the case as explained above, the Registration Board decided for show cause with personal hearing in next Registration Board meeting.**

Case No. 03: M/s. Masfa Industries Pvt. Limited, Lahore (Deferred case of 290th meeting of Registration Board)

M/s. **Masfa Industries (Pvt. Limited), Lahore** has requested for change in specification of already registered products of their following registered products

S. No.	Reg. No.	Name of drug(s) with formulation	Desired specifications	Details of Fee, Registration letter and renewal status	Justification
I	II	III	IV	V	
1	071557	Meofen oral suspension Each 5ml contains:- Ibuprofen……..100mg (BP Specification)	Meofen oral suspension Each 5ml contains:- Ibuprofen……..100mg **(USP Specification)**	Dy. No. 7533 R&I dated 29-05-2019; Fee Rs. 5000/- deposited 13-09-2012 Renewal due: 12-09-2017 Applied: 14-05-2015	We are using USP grade API so, it is more feasible for us to use same product specifications.

2. <u>Decision of 290th Meeting of RB:-</u>

3.

4. Registration Board deferred the above product for submission of comparative analysis of testing methods in BP and USP.

5.

Now the firm has submitted following comparison

PARAMETERS	USP SPECIFICATIONS	BP SPECIFICATIONS
Identification	By 1-UV 2- by retention time comparison.	1- Chemical testing 2- By TLC
Assay by	HPLC	HPLC
Mobile phase	Tetra hydrofuron and water of 2.05 Ph (44% : 56%)	acetonitrile and 0.01M orthophsphoric acid (40 : 60)
Diluent	Methanol and water (1:1)	acetonitrile 0.01M orthophsphoric acid (40 : 60)
Detector	UV 254	UV 220
Column	4.6-mm × 15-cm × 5-µm	3.9-mm × 30-cm × 10-µm
Flow rate	1.0ml/min	2.0ml/min
Injection volume	25µl	10µl
Tailing Factor	NMT 3.0	NMT 2.0
Relative standard deviation	NMT 2.0%	NMT 2.0%
Ph	3.6 --- 4.6	3.6 --- 4.6
Acceptance criteria	90.0% to 110.0%	95.0% to 105.0%

Decision: The Registration Board decided to approve the change of specifications of above product from "BP Specifications" to "USP Specifications".

Case No. 04: Change of Dosage form of M/s. Pacific Pharmaceuticals Limited, Lahore

The request of M/s Pacific Pharmaceuticals (Pvt.) Ltd., Lahore for change of dosage form of their already registered product(s) was deferred in 277th meeting of the Registration Board as per detailed below.

Sr. No.	Name of product with formulation	Reg. No.	Proposed dosage form	Remarks
1	Zimol 40mg Tablet Each tablet contains:- Esomeprazole magnesium trihydrate……..40mg	052824	Zimol 40mg **Capsule** Each **Capsule** contains:- Esomeprazole magnesium trihydrate……..40mg	-
2	Zimol 20mg Tablet Each tablet contains:- Esomeprazole magnesium trihydrate……..20mg	052825	Zimol 20mg **Capsule** Each **Capsule** contains:- Esomeprazole magnesium trihydrate……..**20mg**	Application for registration of Zimol 20mg capsule was considered and approved in 282nd meeting on Export facilitation criteria.

Firm has submitted following documents:-

i. Application with fee of Rs. 20,000/- for this purpose
ii. Form -5
iii. Copy of DML
iv. Last GMP

Decision of 277th Meeting of RB:

Registration Board deferred the request for justification of proposed change in dosage form since existing formulation is also approved in reference regulatory authority authorities

Fresh submission:

Now the firm has submitted that they want to change the dosage form as per their **marketing department requirement.**

The firm has also submitted following documents:

a. Fee Rs. 100,000/- deposited dated 06-07-2020
b. Duplicate Dossier (Form-5)
c. GMP certificate, CoA and stability studies data of M/s. Murli Krishna Pharma Pvt. Limited, India

Decision: The Registration Board did not accede to the above request of firm for change of dosage form of their already registered product(s) since both formulations are approved in reference regulatory authority authorities.

Case No. 5: Delegation of Functions:

Registration Board is competent forum for grant / renewal / cancellation / suspension of registration (including post-registration variations) of drugs under section 7 of the Drugs Act, 1976 and rules framed thereunder. For timely disposal of various functions / post-registration variation cases, Registration Board, in its various meetings, has authorized its Chairman under Rule 24(10) of Drugs (Licensing, Registering & Advertising) Rules, 1976 for deciding such cases. The details of functions delegated in various meetings is as follows:

Sr. No.	Function	Registration Board meeting
1.	Relaxation / exemption in urdu version only for drugs imported for critical ailments like AIDS, cancer, vaccines, sera sutures etc subject to the condition that same shall be printed at any licensed premises prior to marketing.	262
2.	Relaxation / exemption in urdu version only for drugs to be imported in low volume by the firms having manufacturing facility in Pakistan subject to the condition that same shall be printed at any licensed premises prior to market.	262
3.	Export Registration of finished drugs for following categories except Narcotic, Psychotropic drugs and precursor chemicals. • Generic version / me too drugs of already registered formulations. • Formulations which have already been registered for export purposes. • Formulations which are approved by reference regulatory authorities (as approved by Registration Board) and yet not registered for local sale.	262
4.	Change of name of the manufacturer of imported drugs.	262
5.	Increase/ decrease in shelf life of finished drug.	262
6.	Grant of additional packing of already registered same drugs/medicines except injectables.	262
7.	Action initiated on safety of drugs.	262
8.	Change of packing from PVC to Alu-Alu, strip to blister/bottle and vice-versa etc.	262
9.	Changes of source of API-intermediates (pellets/ liquid) and excipients of registered drugs.	262
10.	Constitution of panel of inspector for product specific inspection, GMP inspection etc.	262
11.	Typographic errors in recording minutes and registration letters like composition, brand names, demanded price, pack size etc or other typing mistakes.	262
12.	Change in the packing design/packaging components/ change in label, carton/change in shape, colour of Capsule, Tablets and shape of blister/ aluminum foil.	262
13.	Change of brand names of registered drugs.	262
14.	Correction in formulation in accordance with standard formulations approved by reference regulatory authorities i.e. change from uncoated to film/ sugar coated tablet or vice versa and correction in base / salt / ester / form of API.	276

15.	Correction in specification for issuance of registration letters in accordance with decisions in 264th and 266th meetings.	276
16.	Constitution of Panel for Verification of Stability Data	277
17.	Issuance of show cause notice for already registered contraindicated/Banned injection vitamin K3 10mg/ml (menadione/ menaphthone) for cancellation of registrations	284
18.	Correction in address in registration letter as per DML applicable at that time.	288
19.	Grant of registration of diluents as combo packs for already registered/approved drugs provided that such diluents shall be provided free of cost.	290
20.	Issuance of registration letters in approved cases of ciprofloxacin granules for oral suspension containing ciprofloxacin base where revision / correction of salt form and granules of the formulation is required after submission of requisite fee. All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product. • Soya lecithin • Medium chain triglycerides • Flavor • Sucrose • Purified water.	290
21.	Constitution of panel of inspectors for dosage form specific inspection of manufacturer abroad.	290
22.	In case of change of title of the firm (site remains the same,) issuance of approval letter for change in registration status of products within 10 working days.	290
23.	Approval of change/correction of finished product specifications in different scenarios discussed as under: i. Products registered with manufacturer specifications but formulation exist in official monograph (as decided by Registration Board in 267th meeting) ii. Products registered with any pharmacopeial specification (e.g USP) but formulation do not exist in that particular pharmacopeia but another pharmacopeia (e.g BP).	290
24.	Grant of renewal of registration (locally Manufactured) which have been received within time as required under Rule 27 of Drug (LR&A) Rules 1976.	292
25.	Grant of extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.	295
26.	Disposal of cases regarding change of finished product specification from one pharmacopeia to another pharmacopeia.	New

Decision: **Registration Board deliberated that above referred functions (S No.1-25) are already delegated to Chairman Registration Board. The Board further endorsed/approved continuity of delegation of above functions along with addition of new function at S No. 26 as mentioned above on behalf of Registration Board.**

i. Renewal of registered drugs containing Vitamin-Minerals

Below mentioned registered drugs were deferred in 295th Meeting of Registration Board for evaluation in the light of Vitamin Policy. Accordingly the evaluation along with the Assistant Director (PE&R/PEC) regarding these formulations has been made and details are as under:

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks
M/s S.J&G FazulEllahie (Pvt) Ltd, E/46, S.I.T.E., Karachi.					
1.	050700	**Vivacol Injection** Each 1.5 ml contains:- Iron Sorbitol Citric Acid Complex Eq. To Elemental Iron ….. 75mg Folic Acid ...750mcg Vitamin B12 ..75mcg	23-09-2008	Dy. No. 29658 dated 04-09-2018 10,000	For injectable dosage form approval in reference regulatory agencies is required..
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13 - 14, Sector 15, Korangi Industrial Area, Karachi					
2.	001196-Ex	Polzin Plus 15/500 tablet Each film coated tablet contains:- Glucosamine Sulphate…….500mg Chondroitin Sulphate…….200mg Calcium Carbonate…..75mg Vitamin C…..25mg	01-04-2009	Dy. No. 728 dated 14-03-2019 10000/-	Glucosamine Sulphate and chondroitin sulphate combination is registered as drug
3.	002167-Ex	M-Vit Baby Syrup Each 5ml contains:- Vitamin A as Plminate……150IU Vitamin D3……100IU Vitamin C…….50mg Nicotinamide….10mg D-Penthenol…….5mg Folic Acid…….0.1mg Vitamin B1…..1.0mg Vitamin B2…….1.0mg Vitamin B12….1.0mg	26-06-2009	Dy. No. 728 dated 14-03-2019 10000/-	All the ingredients are below the range of RDA.
M/s. Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Centre Hyderabad Road Landhi Karachi.					
4.	007278	Cofcol Elixir Each 15ml contains:- Paracetamol……..325mg Pseudoephedrine HCL..30mg Dextromethorphan HBr……10mg Chlorpheniramine Maleate…….1mg Vitamin C……50.00mg	18-06-1984 Change of formulation dated 25-01-2002	Dy. No. 3750 dated 16-04-2019 10000/-	Deferred for confirmation of formulation in RRA.
M/s Zafa Pharmaceutical Laboratories Pvt Limited, L-4/1 , A&B , Block 21 Federal B Industrial Area Karachi					

5.	030625	Zecap Capsule 200mg Each Capsule contains:- Vitamin E (dl-Alpha Tocopherol acetate) …200mg	09-06-2004	Dy. No. 2790 dated 05-04-2019 10000/-	Deferred for confirmation of formulation from RRA.
M/s. Wilson's Pharmaceuticals, 387-388 Sector I-9 Industrial Area Islamabad.					
6.	007584	Vitamin-E Tablets Each tablet contains:- Vitamin E…….100mg	11-10-1984	Dy. No. 3110 dated 09-04-2019 10000/-	Deferred for confirmation from RRA.
M/s. Tabros Pharma, Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi.					
7.	024972	**Zeest Tablet** Each tablet contains: Vitamin A …5000IU Vitamin E …100mg Vitamin C …500mg L-Optizinc …20mg Selenium …0.02mg Chromium niacin bounded …0.20mg	09-08-1999	Dy. No. 7167 Dated 24-05-2019 Rs. 10000/-	Quantity of base form of zinc ,chromium and niacin is required from their respective saltf forms.
M/s. Martin Dow Marker Ltd., 7, Jail Road, Quetta ,Pakistan					
8.	033794	Osteocur-C-Effervescent Granules Each sachet of Effervescent Granules contains: Calcium Lactate Gluconate…….1000 mg, Calcium Carbonate…. 327 mg Ascorbic Acid..... 500 mg	06-09-2004 Transfer of registration dated: 03-03-2008 Transfer of registration dated: 07-06-2018	Dy. No. 6598 dated 21-02-2018 10000/-	All the ingredients are between RDA and UL.
M/s. Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi					
9.	009876	Vidaylin-T Tablet Each Tablet Contains: Vitamin A……...2500IU Vitamin D……..400IU Vitamin E……...15IU Vitamin B1…….1.05mg Vitamin B2……1.2mg Vitamin B12…..4.5mcg Niacinamid…...13.5mg Vitamin C…..60mg Folic Acid…….0.3mg Vitamin B6…..…1.05mg	19-09-1988 Change of brand name dated 07-02-2005	Dated 28-08-2018 10000/- Firm submitted evidence of renewal of year 2015 According to the date of change of brand name.	All the ingredients are between RDA and UL
Remarks: Firm is asked to provide the evidence of renewal submission of year 2013 according to the initial registration date. In their reply firm stated that they do not want to maintain the renewal of registration from initial registration dates and will continue the renewal of registration from the date of change of brand name (07-02-2005).Further firm provide the evidence of complete trail of renewal from the aforesaid date of change of brand name. (Reg. No. 009876)					
M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi					
10.	007734	Paramet-Fa GradumetFilmtab Each Tablet Contains:- Vitamin A…4000 IU	17-01-1985 Change of brand name	Dy. No. 15683 dated 26-08-2019 10000/-	All the ingredients are between RDA and UL

		(1.2mg) Vitamin D …400 IU (10mcg) Vitamin C….100mg Vitamin B1 3mg Vitamin B2 2mg Vitamin B6 5mg Vitamin B12 3mg Nicotinamide 10mg Cal. Pentothenate 1mg Calcium (As Calcium Carbonate) 250mg Iodine (As Calcium Iodate) 100mg Copper (As Cupric Chloride) 0.15mg Iron (As Ferrous Sulfate) 60mg	dated 20-09-2013		
Shortcomings: In response to letter dated 15-01-2020, For Paramet-Fa the firm has submitted the renewal letter valid till 17-01-2015 and the evidence of submission of renewal for the next period dated 30-06-2014.					
M/s. Neomedix, Plot No. 5, N/5 National Industrial Zone, Islamabad.					
11.	033698	Nytacon Liquid Each 5ml contains: Vitamin B12 ……..35mcg	31-08-2004	Dy. No. 14896 dated 19-08-2019 10000/-	Evidence of approval of formulation in reference drug agencies
12.	033702	Calfit Syrup Each 5ml contains: Calcium Phosphate (Tribasic)…..210mg Vitamin D3……350 IU	31-08-2004	Dy. No. 14896 dated 19-08-2019 10000/-	Both the ingredients are below the level of RDA.
M/s. Himont Pharmaceutical, 17-Km Ferozpur Road Lahore.					
13.	016046	Enervit Tablet Each tablet contains Vitamin B1… 15mg Vitamin B2… 15mg Vitamin B6… 10mg Vitamin B12… 10mcg Calcium Pantothenate… 25mg Vitamin C … 500mg Folic Acid … 1mg Niacinamde… 100mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Quantity of elemental calcium is required from the calcium Pantothenate.
14.	016047	Enervit Syrup Each 5ml contains:- Vitamin B1… 10mg Vitamin B2… 10mg Vitamin B6… 10mg Vitamin B12… 5mcg Calcium Pantothenate… 3mg Vitamin C … 300mg Folic Acid … 0.5mg Niacinamide… 50mg Lysine Monohydrate … 200mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Lysine Monohydrate is not included in the approved table of UL,remaining ingredients are within UL.
15.	016048	Hikap M Tablet Each tablet contains:	01-11-1994	Dy. No. 17362 dated	All the ingredients are between RDA and UL.

		vitamin A… 5000 IU Vitamin D… 500IU Vitamin B1... 10mg Vitamin B2… 10mg Vitamin B6… 4mg Vitamin B12... 5mcg Vitamin E… 50IU Vitamin C.... 300mg Calcium Pantothenate… 20mg Folic Acid … 1mg Biotin … 300mcg Calcium… 100mg Iron … 50mg Iodine… 100mg Magnesium … 10mg Copper .. 2mg Zinc…. 15mg Maganese… 5mg Chromium… 15mcg Selenium... 15mcg Molybdenum... 15mcg Potassium... 7.5mg Nicotinamide ... 50mg Phosphorus... 25mg		17-08-2019 Rs. 10,000/-	
16.	016049	Hikap M Syrup Each 5ml contains:- vitamin A… 1mg Vitamin D… 1mg Vitamin B1… 10mg Vitamin B2… 10mg Vitamin B6… 1mg Vitamin E… 25IU Vitamin C… 150mg Calcium Pantothenate… 5mg Folic Acid … 0.5mg Biotin … 100mcg Calcium… 50mg Iron … 25mg Iodine… 20mg Magnesium … 5mg Copper .. 1mg Zinc…. 1mg Maganese… 1mg Chromium… 5mcg Selenium... 5mcg Molybdenum... 5mcg Potassium... 2.5mg Nicotinamide ... 20mg Phosphorus... 50mg Choline ... 10mg Inositol... 10mg Lysine Monohydrate... 200mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	1 mg of vitamin D is used in the formulation while UL level of vitamin D is 250mcg.
M/s. Paramount Pharmaceuticals, 36 Industrial Triangle, Kahuta Road, Islamabad.					
17.	033992	Tricos Syrup Each 15ml contains:-	23-09-2004	Dy. No. 17604 dated	Evidence of formulation in Reference Regulatory

		Paracetamol… 325mg Pseudoephedrine HCl… 30mg Dextromethorphan… 10mg Vitamin C… 50mg Chlorpheniramine Maleate… 1mg		16-09-2019 Rs. 10,000/-	Agencies (RRA) is required, in same strength and dosage form.
M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi					
18.	025532	Avelac-C Chewable Tablet Each chewabletablet contains:- Calcium Ascorbate eq. to Vitamin C… 300mg	25/11/1999	Dy. No. 17258 dated 11-09-2019 Rs. 10,000/-	Evidence of approval of formulation by reference regulatory authorities in the same strength and dosage form as applied.
19.	025531	Calix Chewable Tablet Each Chewable tablet contains:- Vitamin A …2500IU Ascorbic Acid …30mg Vitamin D …200IU Vitamin E …15IU Vitamin B1 …0.75mg Vitamin B2 …0.85mg Niacin …10mg Vitamin B6 …1mg Folate …0.2mg Vitamin B12 …0.003mg Biotin …0.02mg Pantothenic Acid …5mg Calcium …50mg Iron …9mg Phosphorus …50mg Iodine …0.075mg Magnesium …10mg Zinc …7.5mg Copper …1mg Sodium …5mg	**25-11-1999** Change of BN: 18-12-2003	Dy. No. 17258 dated 11-09-2019 Rs. 10,000/-	All the ingredients are between RDA and UL.
M/s. Glitz Pharma, Plot No 265 Industrial Triangle Kahuta Road Islamabad.					
20.	077698	Osilex-D Tablet Each film coated tablet contains Ossein Mineral complex……..830mg eq to calcium…..……177.60mg Phosphorous……82.20mg Residual mineral salts…..24.80mg collagen……..…224mg Other Proteins……88.4mg Trace elements F1,Mg,Fe,Nim Cu corresponding to	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	Confirmation of availability of atomic absorption spectrophotometer is required

		Approx…….440mg Hydroxyapatitie Vitamin D..... 400IU			
21.	077699	Osilex-D Suspension Each ml contains Vitamin D……..400IU Ossein mineral complex i.e. Hydroxyaoatite compound (Anhydrous)…….250mg Eq to calcium……..53.50mg Phosphorous……..24.80mg Residual Mineral salt…..7.50mg collagen……..…8750mg other protein…….20mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....132.53mg hydroxyapatite	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	-do-
22.	077700	Osilex-D Suspension Each 5ml contains Vitamin D……400 IU Ossein mineral complex i.e. Hydroxyapatite compound (Anhydrous)…….400mg Eq to calcium……..85.59mg Phosphorous……..39.61mg Residual Mineral salt……...…12mg collagen……107.95mg other protein…….32mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....212mg hydroxyapatite	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	-do-

Remarks:

Firm has been asked to provide following shortcomings:

- Please provide proof of availability in reference regulatory Authority.
- Please confirm the availability of Atomic Absorption for testing of these products.

In their reply firm stated that they have Avanta Atomic Absorption GBC model, serial #GBCN814 manufacturer GBC AVANT AUSTRALIA accessible in their QC Lab for the purpose of testing different type of minerals and is properly calibrated from external source.

M/s. Bloom Pharmaceuticals (Pvt) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar

23.	022580	Zyvit Syrup 120mg Each 5ml contain: Eiastase.....135mg Pepsin……..50mg Papine…….50mg Vitamin B1... 5mg Vitamin B2... 2mg Vitamin B6... 2mg Vitamin B12. 5mcg Nicotinamide… 20mg Cal. Pantothenate…..1mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	Enzymes are used in the formulation which are not fall under the perviwe of Vitamin and mineral policy.

Remarks:

Letter of shortcoming has been communicated to the firm dated 30-07-2019,details are as under:
Differential fee required as renewal of year 2013 was submitted after due date but within sixty days.
Evidence of approval of formulation in reference drug agencies.

Firm has been submitted the differential fee of Rs.10, 000/- , as the renewal application of year 2013 has been submitted late but within 60 days. Further firm did not provide the evidence of approval of formulation in Reference Regulatory Agencies.

M/s. Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar.

24.	023585	Effeco Tonic Each 100ml contains:- Ferric Ammonium Citrate……900mg Folic Acid….10mg Thiamine HCl……20mg Pyridoxine……..40mg Nicotinamide….200mg	06-24-1999	Dy.No.3441 Dated.25/01 /2019 Rs.10000	Quantity of elemental iron is required from Ferric Ammonium Citrate.
25.	030919	Ferropro Tonic Each 10ml contains:- Vitamin A …..6000IU Vitamin D1 …. 1200IU Vitamin B1 …1.3mg Vitamin B2 …0.6mg Vitamin E … 3.0mg Nicotinamide … 13.5mg Ferric Ammonium. Citrate Green…..90mg	05-11-2004	Dy.No.3441 Dated.25/01 /2019 Rs.10000	Quantity of elemental iron is required from Ferric Ammonium Citrate.

Remarks :

Notarized copy of last renewal application of all the products along with fee challan.

M/s. Cirin Pharmaceuticals (Pvt) Ltd., Plot No. 32/2-A Phase III, Industrial Estate, Hattar

26.	015989	Vitacal Extra Sachets Each sachet contains:- Calcium Glycerophosphate…373.3 mg Calcium Carbonate…156.7mg Calcium Pantothenate…15mg Thiamine HCl	**20-09-1994** Transfer of reg to new title: 03-03-2020	Dy. No. 13985 dated 02-08-2019 10000/-	Formulation does not fall under the preview of vitamin and mineral policy.

		(B1)…15mg Riboflavin-5-Phosphate Sodium (B2)…15mg Pyridoxine HCl (B6)…10mg Ascorbic Acid (Vit. C)…100mg Nicotinamide…50mg Sodium Bicarbonate…1000mg Citric Acid...1500mg Sodium Citrate...100mg Saccharin...6mg Dextrose (Anhydrous, Injectable Grade)...3000mg Orange Flavour...500mg			
27.	015990	Vitacal 1000+C Sachets Each sachet contains:- Calcium Gluconate…578mg Calcium Lactate…422mg Ascorbic Acid…500mg Calcium Carbonate…327mg Sodium Bicarbonate…500mg Citric Acid…1000mg Orange Flavour…70mg Saccharin Sodium…20mg Sodium Citrate…100mg Sucrose…6000mg	**20-09-1994** Transfer of reg to new title: 03-03-2020	Dy. No. 13985 dated 02-08-2019 10000/-	Formulation does not fall under the preview of vitamin and mineral policy.
M/s. Jawa Pharmaceuticals (Pvt) Ltd., 112/10 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore					
28.	059911	Liveright Syrup Each 5ml contains:- L-Omithine L-Aspartate …… 300mg Nicotinamide…24mg Riboflavin Sodium Phosphate…0.76mg	02-09-2009	Dy. No. 15851 dated 27-08-2019 10000/-	L-ornithine L-Aspartate are not included in the approved table of UL.
M/s. Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad					
29.	025430	Super-7 Sachets Each sachet contains:- Calcium Carbonate.....550mg Calcium Lactate Gluconate……...250mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12....250mcg Vitamin B1.....2.5mg Vitamin B6.....2.5mg	23-11-1999	Dy. No. 15548 dated 23-08-2019 10000/-	All of the ingredients are between RDA and UL.
30.	025431	Geriaktive-M Capsules Each capsule contains:- Vitamin A (5000 iu).....5000iu Vitamin D.....500iu Vitamin B1.....10mg	23-11-1999	Dy. No. 15548 dated 23-08-2019 10000/-	All the ingredients are between RDA and UL.

		Vitamin B2.....10mg Vitamin C.....300mg Vitamin B6.....4mg Calcium Pentothenate....20mg Vitamin B12.....5mcg Vitamin E.....50IU Folic Acid.....1mg Biotin.....300mcg Nicotinamide.....50mg Iron.....50mg Iodine.....100mcg Copper.....2mg Zinc.....15mg Magnesium.....10mg Manganese.....5mg Chromium.....15mcg Selenium.....15mcg Molebdenum.....15mcg Phosphorus.....25mg Potassium.....7.5mg Calcium.....100mg			
M/s Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area Islamabad					
31.	025040	High-C 1500 Sachets Each sachet contains:- CaCO3.....1000mg Vitamin C.....500mg Vitamin D.....500IU Vitamin B6.....10mg	05-08-1999	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	**Complete**
32.	025039	High-C 1500 Tablet Each tablet contains: CaCO3.....1000mg Vitamin C.....500mg Vitamin D.....500IU Vitamin B6.....10mg	05-08-1999	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	All the ingredients are between RDA and UL.However the confirmation is required either it is effervescent tablet or otherwise.
33.	016037	High- C Plus sachet Each sachet contains:- Thiamine HCl……15mg Riboflavin-5-Phosphate Sodium….15mg Pyridoxine HCl…….10mg Nicotinamide…….50 mg Vitamin C……..100mg Total Calcium …….134.64mg (As Pantothenate, Carbonate/Glycerophospha te / Lactate/ Gluconate)	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	All the ingredients are between RDA and UL.
34.	015666	Nutrition-6 Tablet Each tablet contains: Ferrous Gluconate…250mg Vitamin B1 (Thiamine BP)…100mg Vitamin B6 (Pyridoxine	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Quantity of elemental iron is required from Ferrous Gluconate.

		HCl)…100mg Calcium Glycerophosphate…350mg Folic Acid BP…1.0mg Vitamin B12 (Cyanocobalamine) BP…250mcg			
35.	016036	High-C 1000 Sachet Each sachet contains:- Calcium Lactate Gluconate…1000mg Calcium Carbonate….327mg Ascorbic Acid…….500mg	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	All the ingredients are between RDA and UL.
M/s Nabiqasim Industries (Pvt) Ltd., 17/24 Korangi Industrial Area Karachi					
36.	024971	Multical Plus Sachets Each sachet contains:- Calcium Pantothenate.....15mg Calcium glycerophosphate…373.3 mg Calcium Carbonate...156.7mg Vitamin C.....100mg Vitamin B1.....15mg Vitamin B2.....15mg Vitamin B6.....10mg Nicotinamide.....50 mg	20-07-1999	Dy. No. 10912 dated 08-07-2019 Rs. 10000/-	All the ingredients are between RDA and UL.
37.	024970	Multical 1000 Sachets Each sachet contains:- Calcium Lactate Gluconate .....1000mg Calcium Carbonate...327mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12.....250mcg	20-07-1999	Dy. No. 10912 dated 08-07-2019 Rs. 10000/-	All the ingredients are between RDA and UL.
M/s. Jawa Pharmaceutical (Pvt) Ltd., 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.					
38.	060604	Calchew D Tablet Each chewable tablet contains:- Calcium Carbonate ..,1250mg (eq. to 500mg elemental Calcium) Vitamin D…125IU	21-10-2009	Dy. No. 20030 dated 08-10-2019 Rs. 10000/-	Both the ingredients are below the RDA Level.
M/s. Neomedix,Plot No. 5/N-5 National Industrial Zone, Islamabad.					

39.	034090	Feplus B Liquid Each 5ml contains:- Ferrous Sulphate… 131mg Vitamin C… 125mg Vitamin B2… 1.5mg Vitamin B6… 1.25mg Vitamin B12… 6.25mg Nicotinamide… 7.5mg Dexpanthenol… 2.5mg	27-10-2004	Dy. No. 21666 dated 23-10-2019 Rs. 10000/-	Quantity of elemental iron is required from Ferrous Sulphate.
M/s. Bloom Pharmaceutical (Pvt) Ltd, Plot No. 30 Phase I & II Industrial Estate Hattar.					
40.	016460	Blomic Syrup Each 5ml contains:- Ferrous Gluconate… 129.5mg Vitmain B1… 1mg Vitamin B2… 1mg Vitamin B6… 1.5mg Biotin … 30mcg Nicotinamide… 15mg	21-11-1994 Change of brand name from theron-F syrup on 19-11-1999	Dy. No. 24563 dated 21-11-2019 Rs. 10000/-	Quantity of elemental iron is required from Ferrous Gluconate.
41.	016478	Theron F Capsule Each capsule contains:- Ferrous fumarate… 300mg Vitamin B12…. 7.5mcg Vitamin C …100 mg Vitamin B1…. 10mg Vitamin B2…. 5mg Vitamin B6… 5mg Nicotinamide… 10mg Folic acid… 1mg Calcium Pantothenate… 10mg	21-11-1994	Dy. No. 24563 dated 21-11-2019 Rs. 10000/-	Quantity of elemental iron is required from Ferrous Fumarate. Renewal application submitted late but within 60 days of expiry. Differential Fee shall be submitted
M/s. Irza Pharma (Pvt) Ltd,10.2-Km Lahore Sheikhupura Road P.O Kot Abdul Malik District Sheikhupura.					
42.	007799	Ascorbic Acid 100mg Tablet Each tablet contains:- Ascorbic Acid… 100mg	01-01-1985	Dy. No. 22998 dated 07-11-2019 Rs. 10000/-	Proof of availability in reference regulatory Authority.
43.	007806	K-Vit Tablet Each tablet contains:- Acetamenaphthone… 10mg	01-01-1985 Change of brand name from vitamin K tablet on 15-09-1997	Dy. No. 22998 dated 07-11-2019 Rs. 10000/-	Proof of availability in reference regulatory Authority.
M/s. Olive Laboratories, 52 -S6, National Industrial Zone, Rawat, Rawalpindi					
44.	032615	Enemik Syrup Each 5ml Contains: Ferrous Gluconate…130mg Thiamine HCl(B1)…1.5mg Riboflavin (B2)…1mg Pyridoxine HCl (B6)…1.5mg Nicotinamide…15mg Calcium Pantothenate…1mg L.Lysine HCl…50mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Quantity of elemental iron is required from Ferrous Gluconate.Further L.Lysine is not included in the list of UL table.

45.	032616	Enemik Tablet Each Tablet Contains: Ferrous Fumarate…200mg Thiamine HCl (B1)…2.5mg Riboflavin (B2)…2.5mg Pyridoxine HCl (B6)…2.5mg Cyanocobalamine (B12)…25mcg Nicotinamide…25mg Folic Acid…1mg Calcium Pantothenate…10mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Quantity of elemental iron is required from Ferrous Fumarate.
46.	032617	Olivit Tablet Each Tablet Contains: Thiamine HCl (B1)…15mg Riboflavin (B2)…15mg Pyridoxine HCl (B6)…10mg Cyanocobalamine (B12)…10mcg Nicotinamide…10mg Folic Acid…1mg Calcium Pantothenate…25mg Ascorbic Acid (Vit. C)…100mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	All the ingredients are between RDA and UL.
47.	032618	Olivit Drop Each ml Contains: Thiamine HCl (B1)…3mg Riboflavin 5 Phosphate Sodium (B2)…3mg Pyridoxine HCl (B6)…2mg Cyanocobalamine (B12)…1mcg Ascorbic Acid (Vit. C)…50mg Nicotinamide…10mg Calcium Pantothenate (D-pantothenol)…25mg L.Lysine monohydrate (as HCl)…5mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	All the ingredients are between RDA and UL except L-Lysine which has not in the list of approved UL table.
48.	032619	Olivit Syrup Each 5ml Contains: Thiamine HCl (B1)…10mg Riboflavin 5 Phosphate Sodium (B2)…10mg Pyridoxine HCl (B6)…10mg Cyanocobalamine (B12)…5mcg Ascorbic Acid (Vit. C)…150mg Nicotinamide…50mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	All the ingredients are between RDA and UL except L-Lysine which has not in the list of approved UL table.

		Calcium Pantothenate (D-pantothenol)…3mg L.Lysine monohydrate (as HCl)…20mg			

Submitted for the consideration of Registration Board.

i. Application submitted after due date but within sixty (60) days

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks
M/s. Paradise Pharma, 23-Km Sheikhupura Road, Lahore					
49.	071545	Addol Oral Suspension Each 5ml Contains: Paracetamol…120mg	12-09-2012	Dy. No. 17370 dated 06-10-2017 Rs. 20,000/-	The firm has submitted the renewal application of year 2017 after expiry but within sixty (60) days with prescribed of Rs.20,000/-
50.	071547	Ibuprofen Oral Suspension Each 5ml Contains: Ibuprofen…100mg	12-09-2012	Dy. No. 17370 dated 06	The firm has submitted the renewal application of year 2017 after expiry but within sixty (60) days with prescribed of Rs.20,000/-
51.	071549	Parapipe Elixir Each 5ml Contains: Piprazine (as Citrate)…750mg	12-09-2012	Dy. No. 17370 dated 06	The firm has submitted the renewal application of year 2017 after expiry but within sixty (60) days with prescribed of Rs.20,000/-
52.	071550	Ichthammol Glycerin External Preparation Each 100gm Contains: Ichthammol…10gm Glycerin…90gm	12-09-2012	Dy. No. 17370 dated 06	The firm has submitted the renewal application of year 2017 after expiry but within sixty (60) days with prescribed of Rs.20,000/-
53.	071551	Pydon External Preparation Each 60ml contains: Providone-Iodine…7.5%	12-09-2012	Dy. No. 17370 dated 06-10-2017 Rs. 20,000/-	The firm has submitted the renewal application of year 2017 after expiry but within sixty (60) days with prescribed of Rs.20,000/-

Submitted for the consideration of Registration Board.

Decision: Registration Board deferred the agenda of RRR Section due to paucity of time.

Item No. III Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Locally Manufactured Human Biologicals.	1
B	Imported Human Biologicals from Reference Countries	6
C	Imported Human Biologicals from Non-Reference Countries	5
D	Imported Veterinary Biologicals from Non-Reference Countries	10
E	Miscellaneous/ Deferred cases	85
Additional Agenda		
Total		107

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. Khurram Khalid	AD-I	15
2.	Mr. Saadat Ali Khan	AD-II	38
3.	Mr. M. Zubair Masood	AD-III	54

A: Locally Manufactured Human Biologicals.

1. <u>Priority Registration/ Emergency use Authorization of Tocilizumab for use in Covid-19 patients</u>

Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 decided to allow the submission of registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5F for registration of Tocilizumab in light of approvals granted by the reference regulatory authorities and with following conditions:

a. The applicants can submit their application till 31-07-2020 and these applications will be considered out of queue.
b. Registration Board shall consider grant of registration under proviso of Rules 29(6) (8) of the Drug (Licensing, Registration & Advertising) Rules, 1976 and shall follow precautions/ terms & conditions as adopted by the Reference Regulatory Authorities.
c. The registration holders including those granted registration under Form 5D as a new drug will submit data of product development and 6 months real time stability studies data within one year along with other data as may be required by Registration Board. The data will be considered by Registration Board for further decision.

Accordingly, in light of above decision, a circular was issued vide No. F. 76-DRAP/2020 (PE&R) dated 04-06-2020.

In this context, it is submitted Tocilizumab is a biotechnology product and falls under the category of Biological Drugs as per Schedule-I of DRAP Act, 2012 and requires dedicated biotech facility. Division of Biological Evaluation & Research has received applications from following local manufacturers on Form 5 and Form 5D:

Sr. No.	Name of Manufacturer	Brand Name & Composition	Section
1.	M/s Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore.	Zumab Injection Each 20ml contains: Tocilizumab…….400mg	1. Injection (General) Ampoules 2. Vial Infusion
2.	M/s Welwrd Pharmaceuticals, Hattar.	Tocikon 400mg/20ml Infusion Each vial contains: Tocilizumab…….400mg	Injection Ampoule/ Vial (General)
3.	M/s WnsFeild Pharmaceuticals, Hattar.	Tocizab 400mg/20ml Infusion Each vial contains: Tocilizumab…….400mg	Liquid Injectables (General)
4.	M/s Saffron Pharmaceuticals (Pvt.) Limited, Faisalabad.	Zumacil 80mg/4ml Injection for Infusion Each ml contains: Tocilizumab…….20mg	1. Liquid Injectable Ampoule (General) 2. Liquid Vials/ Small Volume Infusion
5.		Zumacil 200mg/10ml Injection for Infusion Each ml contains: Tocilizumab…….20mg	
6.		Zumacil 400mg/20ml Injection for Infusion Each ml contains: Tocilizumab…….20mg	

1. M/s Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore.
2. M/s Welwrd Pharmaceuticals, Hattar.
3. M/s WnsFeild Pharmaceuticals, Hattar.
4. M/s Saffron Pharmaceuticals (Pvt.) Limited, Faisalabad.

The above mentioned applicants do not have the Biological Section approval nor provided any details of source of drug substance and only provided proposed formulations. M/s Shrooq Pharmaceuticals & M/s Saffron Pharmaceuticals provided the following commitments along with their applications:

a. We are submitting proposed formulation based on physicochemical characteristics of Active & Inactive components of formulation. Before marketing of the product, we will prepare trial/ pilot scale batches for adjustment of said formulation in which proposed quantities of inactive ingredients may vary. After adjustment of formulation, the final formulation shall be submitted to DRAP along with Pharmaceutical Development studies.
b. Before marketing of product, we shall perform/ conduct following studies for our product as per guidelines approved/ recommended by the Registration Board & the same shall be submitted to DRAP for becoming the part of our dossier of said product:
    i. Stability Studies
    ii. Pharmaceutical Development Studies
    iii. Validation of analytical testing method and
    iv. Process Validation.
c. Label claims and prescribing information would be same as approved by reference drug agencies like FDA, TGA, MHLW, EMA and Health Canada.

M/s Welwrd Pharmaceuticals and M/s WnsFeild Pharmaceuticals did not provide any commitments.
The case is placed before the Registration **Board** to seek guidance to deal with such applications lacking basic requirements and information please.

Decision: Registration Board rejected the above mentioned applications of the firms for the grant of registration of Tocilizumab due to non-availability of the requisite manufactuting facilities (Biological Section).

B: Imported Human Biologicals from Reference countries.

1.	**Name of Applicant**	**M/s Servier Research & Pharmaceuticals, Kot Abdul Malik, Ferozwala, District Sheikhupura.**
	DSL details	DSL No. 05-354-0078-033161D dated 28-06-2018 valid till 28-06-2020
	Name of Manufacturer	**Product License Holder:** M/s Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes Cedex, France **Manufacturer:** M/s Lyophilization Services of New England Inc., 25 Commerce Drive-West, Bedford, New Hampshire, 03110, USA **Quality Control and Secondary Packaging:** M/s Exelead, Inc., 6925 Guion Road, Indianapolis, Indiana 46268, USA **Batch Release Site:** Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy, France.
	Brand Name +Dosage Form + Strength	Oncaspar 750U/ml Powder for solution for injection/ infusion
	Composition	Each vial contains: Pegaspargase*……..3750 Units (U)** * The active substance is a covalent conjugate of Escherichia coli-derived L-asparaginase with monomethoxypolyethylene glycol. ** One unit is defined as the quantity of enzyme required to liberate 1µmol ammonia per minute at pH 7.3 and 37^0C.
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Anti-neoplastic Agent
	Shelf life	2 years (2^0C-8^0C)

International availability	Oncaspar 750U/ml Powder for solution for injection/ infusion available in UK.
Alternate Products already registered in Pakistan	Not Available
Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No. 20591, 28874&2503 Dated: 14-10-2019, 01-01-2020&24-02-2020 Rs. 50000/- Dated 14-10-2019
Demanded Price / Pack size	1's Vial/ Not Provided.
General documentation	Legalized CoPP No. 08/19/135377 dated 03-09-2019 issued by EMA.
Remarks of Evaluator (M. Zubair Masood)	• This division has received letters from doctors of INMOL and Shaukat Khanum Memorial Trust indicating that they are using the said product and have found this product satisfactory. They further requested the authorities to make it freely available in Pakistan for patient care.

Moreover, the firm has demanded for Oncaspar brand name which has already been approved in name of M/s Merixil Pharma, Islamabad for solution formulation of above product in 254th meeting of Registration Board but the letter was not issued as the product license holder of said product was changed and the firm did not submit the sole agency agreement from new product license holder. Details are as under:

Following product of M/s Merixil Pharma, Islamabad was approved in 254th meeting of Registration Board as per following details:

Name of Manufacturer	**Brand Name & Composition**	**Document Details/ Pack Size**	**Decision of RB in 254th Meeting**
Sigma-Tau Arzneimittel GmbH Liebherrstr. 22 80538 Munich, Germany	ONCASPAR 3750 IU Injection Each ml of solution for injection contains 750 IU of PEGLASPARGINASE (ANTICANCER)	CoPP No. S 225-1-03/15 dated 29-7-2015 1's Vial	*Keeping in view approval status of the product by EMA, Registration Board approved as per Import Policy for Finished Drugs and confirmation of storage facility of importer.*

After approval by the Board, DBER received an anonymous letter addressed to health Secretary Ministry of NHS&RC Islamabad, regarding registration of Inj. Oncaspar with misleading documentation. The complainant has drawn the attention of ministry towards the registration of Oncaspar injection with concealment/falsified information with malafide intent. The complaint stated that this product is used for treatment of blood cancer in children and the product is very expensive. The said product was approved in 254th Registration Board meeting held on 11th -12th November 2015.The product was approved as Sigma-Tau GmbH manufacturer of the product. At that time the product no longer belonged to Sigma-Tau, as 6 months before the approval by honorable board Baxter acquired Sigma-Tau's Oncaspar and this information was public since 13th May 2015.Later on, Baxalta was acquired by Shire and this information was made public on 11th January 2016.The said product is listed on Shire website in their portfolio www.shire.com and on www.oncaspar.com the shire's resource helpline is provided. As per European Medicine Agency website the Marketing Authorization Holder of the Product is Baxalta Innovation GmbH, Austria & Manufacturer is Shire Pharmaceuticals Ireland Limited. The complainant requested that documentation of the product should be thoroughly scrutinized, as the information was concealed from the honorable Registration Board, and neither this information was provided at any later stage. The importer is trying to get this product registered with the name of a principle that no longer holds the marketing authorization neither manufacturing the product.

Accordingly, DBER issued a letter to the firm to explain their position on 22-03-2018. The firm did not submit any response and after the submission of application for registration of Oncaspar Lyophilized formulation by M/s Servier Research & Pharmaceuticals, Sheikhupura, M/s Merixil Pharma, Islamabad on 25-10-2019 submitted a letter stating the following:

"Market authorization holder & manufacturer of product is changed due to acquisition of previous Sigma-Tau Arzneimittel GmbH Liebherrstr. 22 80538 Munich, Germany by Baxalta GmbH Austria and Manufacturer Shire Pharmaceutical, Ireland & from Oct 2018 ONCASPAR is being purchased worldwide by M/s Servier France.

Merixil Pharma therefore, has no objection to transfer of the registration of above mentioned in the name of Servier Research and Pharmaceuticals (Pakistan) Pvt Limited with their office at 65 Main Boulevard, Gulberg, Lahore with immediate effect."

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of EMA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Registration Board further deliberated that as M/s Merixil pharma, Islamabad has submitted the NOC for transfer of registration of Ocaspar 3750IU Injection (approved in 254th meeting) in name of M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Limited, Lahore, therefore, the board also cancelled the approval of Ocaspar 3750IU Injection from the name of M/s Merixil pharma, Islamabad.		
2.	**Name of Applicant**	**M/s Stallion Pharmaceuticals (Pvt) Ltd.,** **22-L, Johar Town, Lahore.** **Godown Address:** 581-Sundar Industrial Estate, Lahore.
	DSL details	DSL No. 05-352-0066-045476D dated 26-09-2019 valid till 26-09-2021
	Name of Manufacturer	**Product License Holder & Manufacturer:** M/s Japan Bio Products Co., Ltd., (Japan Bio Products Co., Ltd., L'Atelier Fujimitsu) 1-44-4, Tomigaya, Shibuya-ku, Tokyo, Japan. (735-14, Aza Edamitsu, Fujimitsu-mach, Kurume-shi, Fukuoka-ken, Japan.
	Brand Name +Dosage Form + Strength	Laennec, Injection
	Composition	Each 2ml contains: Water-soluble substance of a product of enzymatic human placenta…….112mg
	Finished product specifications	As per Drug Approval and Licensing Procedure in Japan 2016.
	Pharmacological Group	Enzymatic human placenta
	Shelf life	24 months (30^0C)
	International availability	Japan.
	Alternate Products already registered in Pakistan	Not Available
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 7573& 4187 Dated 21-02-2019& 11-03-2020 Rs. 100000/- Dated 21-02-2019
	Demanded Price / Pack size	50's x 2ml Ampoule/ Not Provided.
	General documentation	Legalized CoPP No. 3348 dated 18-10-2018 issued by MHLW, Japan.
	Remarks of Evaluator (M. Zubair Masood)	• The product is used for improvement of hepatic function in chronic hepatic disease. • The submitted CoPP indicates two product license holders & manufacturers, for which the firm submitted the clarification that one is product license holder and other is manufacturer as per following details: **Product License Holder:** M/s Japan Bio Products Co., Ltd., 1-44-4, Tomigaya, Shibuya-ku, Tokyo, Japan. **Manufacturer:** M/s Japan Bio Products Co., Ltd., L'Atelier Fujimitsu 735-14, Aza Edamitsu, Fujimitsu-mach, Kurume-shi, Fukuoka-ken, Japan. • 06 weeks, Multicenter, randomized, open clinical trial to evaluate the efficacy and safety of said product with Choongwae Adelavin 9 inj in 194 patients with alcoholic hepatitis and non-alcoholic steatohepatitis.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of MHLW, Japan (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
3.	**Name of Applicant**	**M/s Novartis Pharma Pakistan Ltd.,**

		15, West Wharf BLDG 1, Karachi
	DSL details	DSL No. 0488 dated 17-01-2018 valid till 26-11-2019
	Name of Manufacturer	**Product License Holder:** M/s Amgen Inc, One Amgen Center Drive, Thousand Oaks, CA 91320 United States of America. **Manufacturer:** M/s Amgen Manufacturing Limited, Carr 31 KM 24 6, Juncos, Puerto Rico 00777-4060, United States
	Brand Name +Dosage Form + Strength	Aerinex Injection 140mg/ml (Erenumab)
	Composition	Each PFS contains: Erenumab…….140mg
	Finished product specifications	Innovator Specifications.
	Pharmacological Group	Monoclonal Antibody
	Shelf life	2 years (2^0C-8^0C)
	International availability	Aimovig 140 mg solution for injection in pre-filled syringe of M/s Novartis Pharmaceuticals Ltd., UK
	Alternate Products already registered in Pakistan	Registration Board in its 286th meeting has already approved another strength of this product i.e. Aerinex 70mg Solution for Injection.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No. 12363& 3056 Dated 18-07-2019& 28-02-2020 Rs. 50000/- Dated 11-07-2019
	Demanded Price / Pack size	1's PFS / Not Provided.
	General documentation	Legalized CoPP No. V8XG-FG5R dated 10-05-2019 issued by USFDA valid till 09-05-2021.
	Remarks of Evaluator (M. Zubair Masood)	As per submitted CoPP, product is license to be placed on the market in exporting country but actually not available in exporting country. The firm has submitted another CoPP issued by EMA which shows that product is licensed and available in European region from the aforementioned manufacturer. Registration Board in its 256th meeting decided as follows: *"if an imported drug is not on free sale in its respective country of origin / manufacture, such product will be registered in Pakistan if the product manufactured in the applied facility is approved by any of the regulatory authorities from USFDA, EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Western Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of former erstwhile Eastern Europe. However, references countries regarding availability of drug / molecule / formulation shall remain the same as specified in 249th meeting of Registration Board."*
Decision: Keeping in view the availability of product in EMA and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
4.	**Name of Applicant**	**M/s Roche Pakistan Limited, 1st 37-B, Block-6, PECHS, Karachi.**
	DSL details	Drug Sale License by way of Whole Sale No. 00750 dated 08-10-2018 valid upto 13-09-2020
	Name of Manufacturer	**Product License Holder:**

		M/s Genetech, Inc. (A member of Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, S San Fran, CA 94080 United States of America U.S. License Number: 1048. **Manufacturer:** M/s BSP Pharmaceuticals SpA, Via Appia Km 65, 561, Latina Scalo (LT) 04013, Italy.
	Brand Name +Dosage Form + Strength	Polivy, Injection
	Composition	Each vial contains: Polatuzumab vedotin-piiq ….140mg
	Finished product specifications	Innovator Specifications.
	Pharmacological Group	Antineoplastic Agent
	Shelf life	24 months (2^0C-8^0C)
	International availability	Polivy 140 mg powder for concentrate for solution for infusion of M/s Roche Products Ltd., UK
	Alternate Products already registered in Pakistan	Not Available
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No. 26689, 4366 & 20995 Dated 10-12-2019, 12-03-2020 & 21-08-2020 Rs. 50,000/- Dated 09-12-2019
	Demanded Price / Pack size	1's Vial/ Price Not Provided.
	General documentation	Original legalized CoPP for Polivy, injection (Certificate#.9X5N-M2TV) with validity till 04-11-2021 issued by USFDA declaring the free sale of applied product in exporting country and GMP compliant status of the manufacturer M/s BSP Pharmaceuticals SpA, Via Appia Km 65, 561, Latina Scalo (LT) 04013, Italy.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
5.	**Name of Applicant**	**M/s Novartis Pharma (Pakistan) Ltd., 15 West Wharf BLDG 1, Karachi.**
	DSL details	Drug Sale License by way of Whole Sale No. 0488 dated 17-01-2018 valid upto 26-11-2019 Copy of receipt of application of for grant of Whole sale license dated 29-11-2019
	Name of Manufacturer	**Product License Holder:** M/s Novartis Pharmaceuticals Corporation, 1 Health Plz, East Hanover, NJ 07936 United States of America, U.S. License Number: 1244 **Manufacturer:** M/s Novartis Pharma Stein AG, Schaffhauserstrasse, Stein 4332 Switzerland.
	Brand Name +Dosage Form + Strength	Pagenax Solution for Injection 120mg/ml
	Composition	Each vial contains: Brolucizumab….6mg/0.05mL (120mg/mL)
	Finished product specifications	Innovator Specifications.
	Pharmacological Group	Antineovascularisation agents
	Shelf life	24 months (2^0C-8^0C)

	International availability	Beovu 120 mg/ml solution for injection of M/s Novartis Pharmaceuticals UK Ltd.
	Alternate Products already registered in Pakistan	Not Available
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No. 27189 & 8139 Dated 16-12-2019 & 20-04-2020 Rs. 50,000/- Dated 16-12-2019
	Demanded Price / Pack size	1's Vial/ Price Not Provided.
	General documentation	Original legalized CoPP for BEOVU, injection (Certificate#.ZMKR-MVSN) with validity till 06-11-2021 issued by USFDA declaring the free sale of applied product in exporting country and GMP compliant status of the manufacturer M/s Novartis Pharma Stein AG, Schaffhauserstrasse, Stein 4332 Switzerland. The certificate also indicate brand name Pagenax for importing country.
	Remarks of Evaluator (M. Zubair Masood)	

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

6.		
	Name of Importer	**M/s Eli Lilly Pakistan (Private) Limited**5A, 5th office Floor 10th Building Floor, Al-Tijarah Centre, 32-1-A Block-6 PECHS, Main Shahrah-e-Faisal Karachi
	DSL details	License No. 1105valid till 18-11-2021
	Name of Manufacturer	**Product License Holder & Manufacturer:** **M/s Eli Lilly and company, Lilly Corporate Center, Indianapolis, IN 46285, USA**
	Brand Name +Dosage Form + Strength	**Emgality™** 100mg/mL solution
	Composition	Each pre-filled syringe contains: galcanezumab……100mg/mL
	Finished product specifications	innovator specifications
	Pharmacological Group	Antimigraine
	Shelf life	24 months when stored at 2-8°C
	International availability	FDA
	Products already registered in Pakistan	New molecule
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No 26686 Dated 10-12-2019 Rs. 50,000/- Dated 04-12-2019
	Demanded Price / Pack size	As per SRO /1's pre-filled syringe
	General documentation	Legalized **CoPP No. RG7R-A7BG**valid till11th July 2021 issued by USFDA.
	Remarks of Evaluator (Mr. Khurram Khalid)	i. 120mg/mL of same drug with same name has already been approved by the Registration Board in its 292nd meeting held on 1-2nd October 2019. ii. The product is innovator and registered in FDA. iii. Indicated for preventive treatment of migraine and episodic cluster headache in adults.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of USFDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

C: Imported Human Biologicals from Non-Reference countries.

1.	**Name of Applicant**	**M/s SMS Corporation, 13 B/1, Block 6, PECHS, Karachi**
	DSL details	DSL No. 0831 dated 08-01-2019 valid till 20-06-2020
	Name of Manufacturer	**Product License Holder & Manufacturer:** M/s Chengdu Rongsheng Pharmaceuticals Co., Ltd., 7 Keyuan South Road, Hi-tech Zone, Chengdu, Sichuan, P.R. China.
	Brand Name +Dosage Form + Strength	Tepron 250IU/2.5ml Vial Human Tetanus Immunoglobulin, Solution for Intramuscular Injection
	Composition	Each dose contains: Protein content……..≤180mg/ml IgG monomer+dimmer content…….≥90.0% Tetanus Antibody Potency…….≥100IU/ml
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Human Tetanus Immunoglubulin
	Shelf life	36 months (2^0C-8^0C)
	International availability	Tetanus Gamma 250IU, Solution for Injection for Intramuscular use of M/s Kedrion SPA, Italy
	Alternate Products already registered in Pakistan	Igantet (Reg. No. 028412) of M/s Hakimsons
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 1248 Dated: 03-05-2017 Rs. 100000/- Dated 02-05-2017
	Demanded Price / Pack size	1's Vial/ Rs. 3182/-
	General documentation	Legalized CoPP dated 28-06-2016 issued by China.
	Remarks of Evaluator (M. Zubair Masood)	• Phase-III clinical trial on 156 patients. • Post Marketing Experience report of 1139 open-injury cases from January, 2002 to June 2003 concluding that efficacy and duration of prophylaxis and the safety of TIG are better than that of Tetanus Toxoid.
Decision: Registration Board deliberated that two firms have already been granted approvals of Tetanus Immunoglobulin on the basis of Periodic Safety Update Report (PSUR) in 282nd & 293rd meetings of Registration Board as PSUR suffices the clinical trial data. Keeping in view the PSUR of above product & valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
2.	**Name of Applicant**	**M/s CCL Pharmaceuticals (Pvt) Ltd., 5-KM, Sheikhupura Road, Tehsil Muridke, District Sheikhupura**
	DSL details	DSL No. 05-354-0077-01978D dated 18-08-2017 valid till 18-08-2021
	Name of Manufacturer	**Product License Holder & Manufacturer:** M/s Aryogen Pharmed, No. 140, Corner of Tajbakhsh Street, 24th KM Tehran-Karaj Makhsous Road, Alborz, Iran.
	Brand Name +Dosage Form + Strength	100mg/4ml Concentrate for solution for infusion
	Composition	Each vial contains: Bevacizumab……..100mg
	Finished product specifications	As per Innovator Specifications

	Pharmacological Group	Anti-neoplastic Agent
	Shelf life	2 years (2^0C-8^0C)
	International availability	Avastin 25mg/ml Concentrate for solution for infusion of M/s Roche Products Limited, UK.
	Alternate Products already registered in Pakistan	Avastin by M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Dy. No. 34036, 6904, 24214 & 3834 Dated 15-10-18, 22-05-19, 18-11-2019 & 09-03-2020 Rs. 50000/- Dated 15-10-2018
	Demanded Price / Pack size	1's Vial (4ml)/ Not Provided
	General documentation	Legalized CoPP No. 665/37455 dated 21-07-2018 issued by Iran.
3.	**Name of Applicant**	**M/s CCL Pharmaceuticals (Pvt) Ltd., 5-KM, Sheikhupura Road, Tehsil Muridke, District Sheikhupura**
	DSL details	DSL No. 05-354-0077-01978D dated 18-08-2017 valid till 18-08-2021
	Name of Manufacturer	**Product License Holder & Manufacturer:** M/s Aryogen Pharmed, No. 140, Corner of Tajbakhsh Street, 24th KM Tehran-Karaj Makhsous Road, Alborz, Iran.
	Brand Name +Dosage Form + Strength	Stivant 400mg/16ml Concentrate for solution for infusion
	Composition	Each vial contains: Bevacizumab……..400mg
	Finished product specifications	As per Innovator Specifications
	Pharmacological Group	Anti-neoplastic Agent
	Shelf life	2 years (2^0C-8^0C)
	International availability	Avastin 25mg/ml Concentrate for solution for infusion of M/s Roche Products Limited, UK.
	Alternate Products already registered in Pakistan	Avastin by M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Dy. No. 34036, 6904, 24213& 3833 Dated 15-10-18, 22-05-19, 18-11-2019 & 09-03-2020 Rs. 50000/- Dated 15-10-2018
	Demanded Price / Pack size	1's Vial (16ml)/ Not Provided
	General documentation	Legalized CoPP No. 665/37455 dated 21-07-2018 issued by Iran.

Biosimilarity data as per WHO guidelines submitted by the firm is as follows:

WHO Biosimilarity Guidelines	**Data Submitted by the firm**

Quality Comparison • Physicochemical Characterization	Characterization: i. Comparative Gel Electrophoresis (Reducing and Non-reducing SDS-PAGE) ii. Peptide Mapping (Primary Structure/ Identity) in comparison with reference standard. iii. Size Exclusion (SE)-HPLC (Monomer, Dimer, Aggragates) (Non-Comparative) iv. Distribution of Charge Variants by Ion Exchange Chromatography (Non-comparative) v. Oligosaccharide profile by Glycan Analysis (Non-comparative) vi. N-Terminal Sequencing (Comparative) vii. Primary Structure by Peptide Mapping (Comparative) viii. C-Terminal Analysis (Comparative) ix. Intact Molecular Mass (Comapartive) x. Protein backbone shape analysis by FTIR (Comparative) xi. Assessment of structural and Hydrodynamic Profile by NMR (Comparative) xii. Secondary Structure Analysis by Circular Dichroism (Comapartive)-
Biological Activity	i. Antibody-Dependent Cell Cytotoxicity (ADCC) and Complement- Dependent Cytotoxicity (CDC) Assay (Comparative)
Immunochemical properties	i. Fc gamma and FcRn binding assay a. SPR binding assays for FcγRIA (Comparative) b. SPR binding assays for FcγRIIA (Comparative) c. SPR binding assays for FcγRIIB (Comparative) d. SPR binding assays for FcγRIIIA (Comparative) e. SPR binding assays for FcγRIIIB (Comparative) f. SPR binding assays for FcRn (Comparative)
Impurities	Process and Product related Impurities (Non- Comparative)
Stability Studies	Provided.
Non-clinical Comparison i. In-vitro Studies ii. In-vivo Studies a. Biological/ Pharmacodynamic activity b. Non- clinical toxicity as determined in one repeat dose toxicity study	Primary Pharmacodynamics: i. VEGF binding Assay (Comparative) ii. C1q binding Assay (Comparative) iii. Fc gamma receptors binding study (Comparative)

	iv. Neutralization of VEGF-mediated Proliferation in HUVEC (Comparative) v. Antibody-Dependent Cell Cytotoxicity (ADCC) and Complement- Dependent Cytotoxicity (CDC) Assay (Comparative) Non-clinical toxicity studies are not provided.
Clinical Comparison	Phase-III, randomized, two-armed, patient and assessor blinded, parallel active controlled non-inferiority clinical trial to evaluate the efficacy and safety of Bevacizumab (Stivant) plus Folfiri-3 in comparison with Bevacizumab (Avastin) plus Folfiri-3 in patients with metastatic colorectal cancer (mCRC) (Interim Report).

Remarks of the Evaluator (M. Zubair Masood):

- The firm has not submitted the non-clinical toxicity studies and provided the reference of EMA guidelines that In-vivo toxicological studies are only required when the biosimilars are produced in a new type of cell or organism, or when the formulation includes new excipients. Having the same expression system and formulation as Avastin, their product is excluded from requirement of toxicological studies.
- The firm has submitted the real time stability data of 24 months for 01 batch, 18 months for 01 batch & 06 months for 01 batch.
- The firm has not submitted the accelerated stability data. The firm submitted that accelerated stability data is only performed on controlled batches, hence not required for on-going batches.
- The firm has submitted the copy of registration letter issued by Iran for Stivant 25mg/mL and it does not indicate the approved shelf life. The firm submitted a copy of letter from their manufacturer which indicates that Iran Food and Drug Administration does not mention shelf life on registration certificate and shelf life is mentioned in submitted CTD at requisite contents including stability studies. The shelf life of the product is 24 months and ongoing stability studies are submitted.
- The firm has already been issued two deficiency letters and the firm has not yet completed the stability study data.

Decision: Registration Board deferred the case for submission of following by the firm:

a) Real time stability data of 24 months for 3 commercial scale batches

b) Accelerated stability data of 06 months for 3 commercial scale batches

4.	**Name of Applicant**	M/s Gene-Tech Laboratories, Head Office: 246/B, PECHS, Block-6, Karachi.
	DSL details	DSL License No. 10725 valid upto 15 Aug 2020.
	Name of Manufacturer	**Product License Holder & Manufacturer:** ANGDE BIOTECH PHARMACEUTICAL Co., Ltd Address: No.78, E-Jiao Street, Dong-E County, Shandong Province, P.R. China
	Brand Name + Dosage Form + Strength	**Retrplase**

		Reteplase for Injection [Recombinant Human Tissue-type Plasminogen Activator Derivative for Injection] Each vial of lyophilized powder contains 18mg of Reteplase for Injection
	Composition	Each vial (10mL) contains: Reteplase (Recombinant Human Tissue-type Plasminogen Activator Derivative)……. 18mg
	Finished product specifications	In house
	Pharmacological Group	Antithrombotics
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Not available in this strength.
	Alternate Products already registered in Pakistan	Same
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A dated 12-9-2018 Form 5-F Dy.No.5720(R&I) DRAP dated 16-2-2018. Fee of 100,000/- dated 31-1-2018.
	Demanded Price Pack size	As per SRO
	General documentation	Legalized CoPP No. SD20170058 issued on 25th October 2017 Legalized
	Evaluator Comments (Mr. Khurram Khalid)	1. The product is **already registered** in the name of Lunar Pharmacia Lahore (Reg. No. 066146) from the same principal. The firm has not provided NOC from the existing importer. However, the firm has provided i. Sole agency agreement in their name and ii. Termination letter for existing importer from the principal. 2. **The strength of reteplase 18mg is not available in reference countries** instead the provided reference product Retavase contains "reteplase 18.1mg" 3. Biosimilarity study data **is not with single reference product** inpre-clinical and clinical trials. The firm has provided two drugs *Rapilysin in* pre-clinical and *Actilyse* in clinical trials. The firm was asked to clarify and they replied that due to different requirements of non-clinical and

		clinical trials different reference drugs were used. However, it is pertinent to mention that both the reference products are not available in required strength 18mg and the product Actilyse is *alteplase* instead of *reteplase*. The firm requested to take the agenda in Reg. Board meeting.
Decision: **Registration Board deferred the case for submission of following by the firm:** **a) NOC for transfer of registration from existing registration holder i.e. M/s Lunar Pharmacia, Lahore.** **b) Evidence of approval of above formulation in any of reference regulatory authorities.** **c) Complete biosimilarity data in comparison with Innovator.**		
5.	Name of Importer	M/s Genome Pharma, Rawalpindi. House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. **Godown:** C-19, Main Commercial, Access Road, RCCI Industrial Estate Rawat, Rawalpindi.
	DSL details	License No.01-374-0176-035673D valid upto 28th August, 2020.
	Name of Manufacturer	**Product License Holder&Manufacturer:**M/s Blau Farmacêutica S.A2833Raposo Tavares Road.,Barro Branco – Cotia Sao Paulo – Brazil.
	Brand Name Dosage Form Strength	**Filgrastine®** Solution for injection Each dose contain; Filgrastim(rHu G-CSF)……..300µg/ Filgrastim…… 30000000 UI/mL
	Composition	Each syringe contains; Filgrastim(rHu G-CSF)……..300µg/ Filgrastim…… 30000000 UI/mL
	Finished product specifications	In-house (The product is available in Japanese Pharmacopeia)
	Pharmacological Group	colony-stimulating factors
	Shelf life	24 months when stored at 2-8°C
	International availability	Neupogen
	Products already registered in Pakistan	Neupogen
	Type of Form Dy. No. & Date Fee submitted	Form 5-A Dy.No.2040(R&I) dated 26-02-2019 Rs.100,000/-
	Demanded Price / Pack size	1's PFS/
	General documentation	• Legalized CoPP issued by ANVISA (National Agency of

		Sanitary Surveillance of Brazil) dated valid till 03/2020.
	Remarks of Evaluator	Detailed below

Bio-similarity studies of the finished product with Granulokine by Amgen .	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	Primary Structure: ***i.*** PeptidemappingbyLC-ESI-MSandMS/MS- ***ii.*** N/C-TerminalSequencingbyMALDI-ISD– • Disulphide bonds analysis by LC-ESI-MS and MS/MS - Work Package 01c • Molecular weight and size by mass spectrometry • Spectroscopic profile by circular dichroism (CD) • Aggregation state analysis by SEC-MALLS • Electrophorectic profile by SDS-PAGE under reducing and non-reducing conditions • Aggregation state analysis by SEC-MALLS • Aggregation state analysis by HPLC-SEC
Biological Activity	Assay of M-NFS-60 cell proliferation for potency determination
Impurities	Impurity profile by reversed phase chromatography (HPLC-RP)
Non-clinical Studies	• Local tolerance due to endovenous and subcutaneous exposure to Filgrastine® when compared to Granulokine® (reference substance) in rabbits. • Biological activity from subcutaneous exposure to Filgrastine® when compared to Granulokine® (reference substance) in a model of experimental neutropenia induced in rats. • The toxic and immunogenic potential, the local tolerance, and the toxicokinetic profile resulting from the daily subcutaneous exposure to Filgrastine®, when compared to the reference substance (Granulokine®) in rats
Clinical Studies	**Phase-I: (comparative)** A randomized, crossover, double-blind clinical trial which comparedincreased leukocyte numberpharmacodynamic effect and pharmacokinetic effect of Filgrastim in plasma to prove the interchangeability oftest products (T1 and T2) by Blausiegel compared to the product **Granulokine®** by Roche, in 24 women whounderwent mastectomy, and also to check the incidence of adverse events. Assessment of pharmacokinetic and pharmacodynamic parameters of the filgrastine drug (filgrastim) of laboratório blau farmacêutica s/a. compared to the granulokine drug of laboratório produtos Roche.
Phase-II:	**Not summitted**
Phase-III:	
Phase-IV:	(Non-comparative) A review of medical records, retrospective, multicenter, to describe efficacy and treatment standards for patients with lymphohematopoietic malignancies receiving filgrastine® in Brazil, before hematopoietic stem cell autologous transplantation

Remarks of Evaluator (Mr. Khurram Khalid)

1. As per record, the product with brand name is already registered with Reg. No. 066169 in the name of Pharmatec Pakistan (Pvt) Ltd., Karachi manufactured by Blausiegel Industrria E Comercio Ltda. Cotia-Sp-Brazil. The firm was asked for clarification and the firm has submitted following clarification from Manufacturer;

"Blau Farmacêutica S.A clarifies that it had an agreement with Pharmatech, Pakistan Pvt Ltd., and decided not to continue it for product distribution in Pakistan. Therefore, the business plan presented by Pharmatech did not meet Blau business, prospects and strategy in this territory. For this reason Blau informed that the mentioned ***agreement settled with Pharmatech was terminated on March 2018 as of the letter of termination****, with the termination of the commercial relationship between the parties and the termination of rights and obligations with respect to marketing Blau product by Pharmatech in Pakistan. As a result of the termination of said agreement, Blau requested Pharmatech to cancel the registration of its product with in the competent aauthories in Pakistan. Pharmatech has expressly acknowledged that the parties granted each other the most complete, total and unrestricted discharge with respect to the rights and obligations contained in the agreement and may no longer claim any right as appropriate."*

Moreover, the firm has submitted

i. Sole Agency Agreement
ii. Termination letter in the name of M/s Pharmatech Pakistan (Pvt) Ltd from the manufacturer.

2. The firm was asked to submit application considering SOPs of 283rd meeting (revised in 292nd meeting of reg. Board.), if it is transfer case. The firm, however, has replied as detailed above (Pt. No. 1).
3. CoPP was valid at the time of application submission but now it is expired.
4. Biosimilarity data as per 278th meeting of Registration Board is not provided.

For biosimilarity data the firm has submitted that

"Filgrastine is a biosimilar to the originator Granulokine, for which the extensive in vitro comparative biosimilarity data has ben provided. Our product was registered in the country of origin, Brazil, on 30-03-2005 along with Chile, Ecuador, Uruguay and Vietnam long before the WHO guidelines for Biosimilar drugs was published in TRS 977, 2013.

As per the decision of the DRAP in its meeting no 278th held on 29-31 january,2018 in section 2(b) the importer shall provide the guidelines for evaluation of biotherapeutics in the country of export (non-reference authorities) as evidence that the submitted data is in accordance with said guidelines.

In this regard it is submitted that filgrastine was registered and in ***use in Brazil since 30-3-2005,*** *thus the product has a fifteen year history of successful use in patients*

When the ***WHO and EU guidelines were available from 2013 onward****, the manufacturer decided to conduct animal test and crossover the test to satisfy the new requirements.*

The manufacturer has done extensive in vitro and in vivo study to prove the comparative biosimilarity of its product applicable at the initial time of registration i.e. 2005. And after 15 years of use in 5 countries, it is to be considered on its merit"

Decision:

Registration Board deferred the case for submission of following by M/s Genome Pharma, Rawalpindi:

a. **Valid legalized CoPP**
b. **The guidelines for evaluation of biotherapeutics in Brazil, as evidence, that the submitted data is in accordance with said guidelines.**

Registration Board further decided to issue show cause notice to M/s Pharmatech Pakistan (Pvt.) Ltd., Karachi regarding the cancellation of their authorization for registration of Filgrastine Injection by M/s Blau Farmacêutica S.A, Brazil.

C: Imported Veterinary Biologicals from Non-Reference countries.

1.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Me Fluvac H5 Reassortant Avian Influenza Inactivated Bivalent Virus Vaccine
	Composition	Each dose contains: rgA\chicken\Egypt\M 7212B/2013 (H5N1)…….. ……$\geq 10^8$ EID_{50}/dose before inactivation rgA\Duck\Egypt/M 2583D\2010 (H5N1)…….. ……$\geq 10^8$ EID_{50}/dose before inactivation
	Finished product specifications	As per Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt, Kuwait
	Alternate Products already registered in Pakistan	Otto Fight Flu Vac (Reg. No. 092197) of M/s Ottoman Pharma, Lahore has H5N1 in its composition.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 7816, 18843, 27815 & 31230 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 22-02-2019
	Demanded Price / Pack size	500ml (1000doses) Plastic Bottle/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 26-03-2018 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Registration Board deferred the case for submission of scientific immunological relevance of rgA\chicken\Egypt\M 7212B/2013 (H5N1) & rgA\Duck\Egypt/M 2583D\2010 (H5N1) strains in Pakistan.		
2.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt

	Brand Name +Dosage Form + Strength	Mevac ND LaSota Live attenuated Newcastle Disease Virus Vaccine (NDV-LaSota)
	Composition	Each dose contains: Lyophilized live attenuated Newcastle Disease Virus (NDV-LaSota)……$\geq 10^6$ EID_{50} at release.
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Hipraviar S of M/s Hipra Pakistan Limited.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5208 , 18843, 27815 & 31228 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	1000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 01-10-2018 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Keeping in view valid legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
3.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Mevac ND LaSota Live attenuated Newcastle Disease Virus Vaccine (NDV-LaSota)
	Composition	Each dose contains: Lyophilized live attenuated Newcastle Disease Virus (NDV-LaSota)……$\geq 10^6$ EID_{50} at release.
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Hipraviar S of M/s Hipra Pakistan Limited.

	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5209 , 18843, 27815 & 31229 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	5000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 01-10-2018 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Keeping in view valid legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
4.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Mevac IB Var2 Lyophilized Live Avian Infectious Bronchitis Vaccine variant 2 (EG/IBV12)
	Composition	Each dose contains: Live Avian Infectious Bronchitis variant virus (EG/IBV12)……$\geq 10^{3.5}$ EID_{50}
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Mevac ND+IB of M/s Bromed Animal Health has inactivated Avian Infectious Bronchitis variant 2 virus.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5210 , 18843, 27815 & 31224 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	1000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 13-01-2019 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	

Decision: Registration Board deferred the case for submission of exact strain name of Infectious Bronchitis Virus and its scientific immunological relevance in Pakistan.		
5.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Mevac IB Var2 Lyophilized Live Avian Infectious Bronchitis Vaccine variant 2 (EG/IBV12)
	Composition	Each dose contains: Live Avian Infectious Bronchitis variant virus (EG/IBV12)…….$\geq 10^{3.5}$ EID_{50}
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Mevac ND+IB of M/s Bromed Animal Health has inactivated Avian Infectious Bronchitis variant 2 virus.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5211 , 18843, 27815 & 31225 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	5000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 13-01-2019 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Registration Board deferred the case for submission of exact strain name of Infectious Bronchitis Virus and its scientific immunological relevance in Pakistan.		
6.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Mevac ND Elite Live attenuated Newcastle Disease Virus Vaccine (NDV2-NDV60)
	Composition	Each dose contains: Lyophilized live attenuated Newcastle Disease Virus (NDV2-NDV60)……$\geq 10^6$ EID_{50} at release.
	Finished product specifications	Ph. Eur. Specs

	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Strain is not available as per record.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5206 , 18843, 27815 & 31224 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	1000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 01-10-2018 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Registration Board deferred the case for submission of exact strain name of Newcastle Disease Virus and its scientific immunological relevance in Pakistan.		
7.	**Name of Applicant**	**M/s Bromed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, Lahore.**
	DSL details	DSL No. 05-352-0066-037660D dated 18-10-2018 valid till 18-10-2020
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (ME-VAC), Second Industrial Zone, Extension Part No. 21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	Mevac ND Elite Live attenuated Newcastle Disease Virus Vaccine (NDV2-NDV60)
	Composition	Each dose contains: Lyophilized live attenuated Newcastle Disease Virus (NDV2-NDV60)……$\geq 10^6$ EID_{50} at release.
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	Strain is not available as per record.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 5206 , 18843, 27815 & 31224 Date: 22-02-2019, 26-09-2019, 20-12-2019 & 22-01-2020 Rs. 100000/- Date: 03-05-2019
	Demanded Price / Pack size	5000doses Vial/ De-controlled
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 01-10-2018

		• Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer. • Legalized copy of registration license of above product for export issued by Egypt indicating demanded pack size.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: Registration Board deferred the case for submission of exact strain name of Newcastle Disease Virus and its scientific immunological relevance in Pakistan.		
8.	**Name of Applicant**	M/s BroMed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, DistrictLahore.
	DSL details	DSL License No.05-352-0066-037660D valid upto 18-10-2020.
	Name of Manufacturer	Middle East for Veterinary Vaccines (ME-VAC) Second Industrial Zone-Extention Part No.21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	**MEVAC Multi IB+H9+ND** Suspension
	Composition	Ingredients per dose (0.5ml): Inactivated Infectious Bronchitis Virus IBV: Classical (IBV-26 MEVAC – M41), IB Variant type 1 (ME/IBV-VAR1-2017)IBV, IB Variant type 2 Eg/1212B)…… $\geq 10^7$ EID_{50}/dose before inactivation. Inactivated Avian Influenza H9N2 A/chicken /Egypt/ME 543V /2016 (H9N2)……. $\geq 10^{8.5}EID_{50}$ /dose before inactivation (Dose is equal $\geq$ 128 HIU) Inactivated Newcastle Disease virus NDV/Chicken/Egypt/11478 AF/2011……. $\geq 108^{.5}EID_{50}$ /dose before inactivation (Dose is equal $\geq$ 128 HIU)
	Finished product specifications	As per Innovator
	Pharmacological Group	Biologicals
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	N/A
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.15185(R&I)DRAP dated 29-6-2020. Fee of 95,000/- dated 29-6-2020.
	Demanded Price Pack size	500ml Vial
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized FSC dated 17-10-2019 • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer.
	Evaluator Comments (Mr. Khurram Khalid)	1. The product was previously taken in 258th meeting of Reg. Board wherein the board decided as under; "*Deferred for submission of original legalized documents: CoPP/ FSC along with GMP."* The firm submitted the documents on 22nd January 2020. However, the brand name and composition were changed in FSC. Now the firm has submitted fresh application with full fee.

Decision: Registration Board deferred the case for submission of scientific immunological relevance of Classical (IBV-26 MEVAC – M41), IB Variant type 1 (ME/IBV-VAR1-2017) IBV, IB Variant type 2 Eg/1212B), H9N2 A/chicken /Egypt/ME 543V /2016 (H9N2) & NDV/Chicken/Egypt/11478 AF/2011 strains in Pakistan.		
9.	**Name of Applicant**	M/s BroMed Animal Health, 246/A, West Wood Colony, Thokar Niaz Baig, District Lahore.
	DSL details	DSL License No.05-352-0066-037660D valid upto 18-10-2020
	Name of Manufacturer	Middle East for Veterinary Vaccines (ME-VAC) Second Industrial Zone-Extention Part No.21, 22, 24, 25 El Salhya El Gdeda, Elsharkya Governorate, Egypt
	Brand Name +Dosage Form + Strength	**Aphthovac-Tri** Suspension
	Composition	Ingredients perdose (2ml): Inactivated FMD Virus Serotype A/Egy/1/2011 (A Iran 05) (4 ug of viral protein /dose which is equivalent to 6 PD_{50}per dose) Inactivated FMD Virus Serotype O/Egy-4-2012 (O Pan-Asia 2) (6 ug of viral protein /dose which is equivalent to 6 PD_{50}per dose) Inactivated FMD Virus Serotype Asia 1/Shamir (5 ug of viral protein /dose which is equivalent to 6 PD_{50}per dose)
	Finished product specifications	BP
	Pharmacological Group	Veterinary Biologic
	Shelf life	24 Months (Store at 2°C to 8°C)
	International availability	Egypt
	Alternate Products already registered in Pakistan	**ARRIAH-VAC**(Foot And Mouth Disease Vaccine Inactivated Oil Adjuvant Containing Serotypes A, O, Asia-1). By Mustafa Brothers
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.15186(R&I)DRAP dated 29-6-2020. Fee of 100,000/- dated 29-6-2020.
	Demanded Price Pack size	50mL(25 doses) vial
	General documentation	• Valid Legalized GMP Certificate dated 18-03-2019 valid till 17-03-2022. • Legalized Registration License valid till 05-11-2021. • Legalized copy of manufacturing license of M/s Middle East for Veterinary Vaccines (ME-VAC) indicating address of manufacturer.
	Evaluator Comments (Mr. Khurram Khalid)	1. The Registration License of the product indicate clearly**"For Export"** status. Moreover, it is mentioned that the product is approved in Arabrepublic of Egyptunder reg. No. 833in 6/11/2018. 2. The stability data is of R&D batches and commercial scale batches are not available with the firm. 3. The product was previously taken in 258th meeting of Reg. Board wherein the board decided as under; "*Deferred for submission of original legalized documents: CoPP/ FSC along with GMP."* The firm submitted the documents on 22nd January 2020. However, the brand name and composition were changed in Registration License. Now the firm has submitted fresh application with full fee.

Decision:

Registration Board deferred the case for submission of following by the firm:

a. **Valid Legalized Free Sale certificate indicating availability of product in country of origin.**
b. **Scientific immunological relevance of Serotypes A/Egy/1/2011 (A Iran 05), O/Egy-4-2012 (O Pan-Asia 2) & Asia 1/Shamir of FMD virus in Pakistan.**

10.	**Name of Importer**	M/s Forward Solutions (Animal Health Company) Plot No.19-B, Off Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore-Pakistan
	DSL details	DSL No. 05-352-0066-028137D valid till 10 Feb 2020
	Name of Manufacturer	**ATAFEN** Ata Fen Veteriner Malzemeleri Hayvancilik Paz. San. Ve Tic. A.S. OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey
	Brand Name +Dosage Form + Strength	**VBR K99 + C,** Bacterin toxoid vaccine Each 1ml contains: *Escherichia coli* K99 ≥ 100 AU *Clostridium perfringens* Type C ≥ 10IU Beta antitoxin
	Composition	Each 1ml contains: *Escherichia coli* K99 ≥ 100 AU *Clostridium perfringens* Type C ≥ 10IU Beta antitoxin
	Finished product specifications	BP Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 Months (Store at $2^{o}C$ -$8^{o}C$)
	International availability	Turkey
	Products already registered in Pakistan	N/A
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.559/R&I dated 13th March, 2018 30thNov, 2018 Fee Submitted: Rs.100,000/-
	Demanded Price / Pack size	Decontrolled/ 30mL (15 doses)
	General documentation	• Legalized letter of Authorization • Legalized Free Sale permission certificate for veterinary medicinal products issued by Ministry of Agriculture and Forestry • Legalized GMP Certificate having Certificate No.GMP/TR/V/Yi/S0123/2018 issued by Ministry of Agriculture and Forestry General Directorate of Food and Control, Turkey valid till 22nd November 2020.

	Remarks of Evaluator (Mr. Khurram Khalid)	1. For shelf life of 24 Months, the firm has submitted 32 months stability data with time interval of 0,4,8,12,16,20,24,28 and 32 which compiles to the specifications. 2. The Free Sale Certificate does not mention composition and pack size. The firm has submitted undertaking that they will submit the required FSC mentioning composition and pack size before registration.

Decision: Registration Board referred the case to Ministry of National Food Security and Research for their opinion regarding the requirement of product in Pakistan.

D: Local Veterinary Biologicals

Sr. No.	**Name and address of product manufacturer (Applicant)**	**M/s Ottoman Pharma** 10 km, Raiwind Road, Lahore.
1.	Brand Name +Dosage Form + Strength	OTTO FLU VAC A/B Injectable Emulsion Avian Infuenza Viruses (AIVs) H7 & H9
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.11554 & 6614 Date:05-03-2019 & 20-05-2019 Rs. 20,000/- Date: 05-03-2019
	Composition	Each dose contains: Inactivated AIV H7N3[Not less than $EID_{50}10^9$/ml…..0.075ml Inactivated AIV H9N2[Not less than $EID_{50}10^9$/ml…..0.075ml
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	As per Innovators spec.
	Shelf Life	12 Months (2-8^{0}C)
	Document Details	i. Copy of DML No. 000502, Date of issue 05-08-2017 ii. Fee Challan Rs. 20,000/- iii. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	Products already registered in Pakistan	Not Available as per record
	Remarks of Evaluator (M. Zubair Masood)	
Decision: **Registration Board deferred the case for submission of following by the firm:** **a. Scientific justification of use of H7N3 and H9N2 in single product.** **b. Notarized copy of valid GMP certificate.** **c. Application on Form-5D being new product.** **d. Differential fee of Rs. 30000/-**		
2.	**Name and address of product manufacturer (Applicant)**	**M/s Ottoman Pharma** 10 km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	OTTO ND+H5 Injectable Emulsion Avian Infuenza Viruses (AIVs) H5 & New Castle Disease Virus
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.11555 & 6614 Date:05-03-2019 & 20-05-2019 Rs. 20,000/- Date: 05-03-2019
	Composition	Each dose contains: Inactivated Newcastle Disease Virus containing EID_{50} not less than $10^{7.0}$/ml and HAU not less than 64…..0.06ml Inactivated AIV H9N2 containing EID_{50} not less than $10^{7.0}$/ml and HAU not less than 64…..0.06ml
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	As per Innovators spec.

	Shelf Life	12 Months (2-8^{0}C)
	Document Details	i. Copy of DML No. 000502, Date of issue 05-08-2017 ii. Fee Challan Rs. 20,000/- iii. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	Products already registered in Pakistan	Not Available as per record.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: **Registration Board deferred the case for submission of following by the firm:** **a. Scientific justification of use of H7N3 and H9N2 in single product.** **b. Notarized copy of valid GMP certificate.** **c. Application on Form-5D being new product.** **d. Differential fee of Rs. 30000/-**		
3.	**Name and address of product manufacturer (Applicant)**	**M/s Ottoman Pharma** 10 km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	OTTO FC Armor Injectable Emulsion
	Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.17461 & 6614 Date:07-03-2019 & 20-05-2019 Rs. 20,000/- Date: 07-03-2019
	Composition	Each dose contains: Inactivated Bacterial suspension (dry weight 1.5g/L or 1.5 x 10^{11} (CFUs/ml)…….0.25ml
	Pharmacological Group	Veterinary vaccine
	Finished Product Specification	Ph. Eur. spec.
	Shelf Life	12 Months (2-8^{0}C)
	Document Details	i. Copy of DML No. 000502, Date of issue 05-08-2017 ii. Fee Challan Rs. 20,000/- iii. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	Products already registered in Pakistan	AviPro 108FC3 Platinum of M/s Golden Harvest, Karachi.
	Remarks of Evaluator (M. Zubair Masood)	
Decision: **Registration Board deferred the case for submission of following by the firm:** **a. Evidence of approval of Bacterial Vaccine section.** **b. Notarized copy of valid GMP certificate.**		

E: Miscellaneous/ Deferred Cases.

Evaluator: AD-III

1. Registration of Imported Human Biologicals from reference countries applied by M/s Eli Lilly Pakistan (Private) Limited, Karachi in their name from M/s Ali Gohar & Company (Pvt.) Ltd., Karachi.

M/s Eli Lilly Pakistan (Private) Limited, Karachi applied for the registration of following human biologicals in their name from M/s Ali Gohar & Company (Private) Limited, Karachi as per following details:

Sr. No.	Brand Name & Composition	Name of Manufacturer	Dy. No. Date of Application Fee Status Pack Size
1.	Humalog (Insulin lispro 100U/ml) Solution for Injection Each ml contains: Insulin Lispro……..100units (equivalent to 3.5mg)	**Product License Holder:** M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Manufacturer:** M/s Eli Lilly and Company, Indianapolis, Indiana 46285, USA. **Secondary Packaging & Batch Release:** M/s Lilly S.A., Avda. de la Industria, 30, 28108 Alcobendas, Madrid, Spain.	Dy. No. 6007, 23773 & 4407 Date: 13-05-2019, 13-11-2019 & 13-03-2020 Rs. 100,000/- Date: 13-05-2019 1's Vial (10ml)
2.	Humulin 30/70 100UI/ml Suspension for Injection Each 3ml cartridge contains: Insulin (as Human rDNA biosynthetic insulin)……..100IU/ml	M/s Eli Lilly Italia S.P.A., Gramsci, 731-733- 50019 Sesto Fiorentino (Firenze), Italy.	Dy. No. 6006, 23774 & 4407 Date: 13-05-2019, 13-11-2019 & 13-03-2020 Rs. 100,000/- Date: 13-05-2019 1's Cartridge (3ml) 5's Cartridge (3ml)

The firm has submitted the following documents as per SOPs formulated in 283rd meeting revised in 292nd meeting of Registration Board:

Sr. No.	SOPs formulated in 283rd Meeting revised in 292nd meeting	Documents submitted by the firm
1.	Application on Form 5F with required fee as per relevant SRO	Form-5F and fee Challans of Rs. 100000/- each are provided.
2.	Copy of registration letter and last renewal status.	Copy of initial registration letter of Humalog dated 21-04-1999. Copy of approval of change of source dated 20-09-2005. Copy of last renewal submission of Humalog dated 23-07-2015. Copy of initial registration letter of Humalog dated 05-05-1999. Copy of last renewal submission of Humalog dated 28-02-2019.
3.	Termination letter (original) from manufacturer for previous importer.	Original Termination letter of Humalog from manufacturer for previous importer dated 21-02-2020.

		Original Termination letter of Humulin 70/30 from manufacturer for previous importer dated 14-01-2019.
4.	Authority letter/sole agent letter (original) from manufacturer.	Original Authorization letter of Humalog dated 21-02-2020. Original Authorization letter of Humulin 70/30 dated 14-06-2019.
5.	Document confirming NOC (issued within last 6 Months) from existing registration holder permitting for registration of product to another importer.	No Objection certificates from M/s Ali Gohar & Company (Private) Limited, Karachi dated 01-04-2019 for both products.
6.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized CoPP No. 01/19/128490 dated 14-02-2019 for Humalog issued by EMA. Legalized CoPP No. CPP/2019/152 dated 28-01-2019 for Humulin70/30 issued by Italian Medicine Agency.
7.	Undertaking that the provided information/ documents are true/ correct.	Provided.

In this context, it is submitted that there are two manufacturing sites mentioned on CoPP of Humulin 70/30 for which the firm submitted that dual sourcing is allowed internationally/ in Europe. Therefore, Italian Medicine Agency has mentioned both the sites. However, for their product only M/s Eli Lilly Italia, Italy is applicable and same has already been approved for the said product vide DRAP letter No. 3-80/2015-DDC(BD)(M-264) dated 06-03-2017.

Decision: Keeping in view valid legalized CoPPs indicating product availabilities in country of origin, approval of EMA & Italian Medicine Agency (Reference Regulatory Authorities) and NOC from M/s Ali Gohar & Company (Private) Limited, Karachi; Registration Board cancelled the registrations from the name of M/s Ali Gohar & Company (Private) Limited, Karachi and granted the registrations in the name of M/s Eli Lilly Pakistan (Private) Limited, Karachi as per current Import policy for finished drugs subject to price confirmation from Costing & Pricing division and verification of cold storage facility. Before issuance of registration letter, NOC will be re-confirmed from M/s Ali Gohar & Company (Pvt.) Ltd., Karachi as it was issued in April, 2019.

2. Imported Human Biological from Non-reference country applied by M/s Amson Vaccine & Pharma (Pvt) Ltd., Islamabad deferred in 291st meeting of Registration Board.

Following product of M/s Amson Vaccine & Pharma (Pvt.) Ltd., Islamabad was deferred in 291st meeting of Registration Board as per following details:

Name of Applicant	**M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.**
DSL details	DSL License No.920-ICT/2013 dated 02-08-2018 valid upto 01-08-2020.
Name of Manufacturer	M/s Yuxi Walvax Biotechnology Co., Ltd., No. 83 South Dongfeng Road, High & New Technology Industries Development Zone, Yuxi City, Yunnan Prov., China.
Brand Name +Dosage Form + Strength	Group ACYW 135 Meningococcal Polysaccharide Vaccine (freeze-dried), for Injection
Composition	Each single human dose (0.5ml) contains:

	Meningococcal Group Apolysaccharide.....50µg Meningococcal Group C polysaccharide.....50µg Meningococcal Group Y polysaccharide.....50µg Meningococcal Group W135 polysaccharide.....50µg **Diluent:** Water for injection.....0.5ml
Finished product specifications	Chinese Pharmacopoeia
Pharmacological Group	Meningococcal Polysaccharide Vaccine
Shelf life	24 Months (2^oC to 8^oC)
International availability	Menomune ACYW135 of M/s Sanofi Pasteur, USA
Alternate Products already registered in Pakistan	Menvac ACYW of M/s Sind Medical Store, Karachi.
Type of Form Dy. No. Date of Application, Fee submitted	Initially Form-5 F then Form-5A Dy.No.8969, 15567 & 16548(R&I) Dated: 27-02-2019, 26-08-2019 & 02-09-2019 Rs. 100,000/- Dated: 27-02-2019.
Pack Size/ Demanded Price	1's Vial (lyophilized powder) + 1's Vial (Diluent)/ As per DPC
General documentation	Legalized CoPP No. 2018-043 dated 06-08-2018 valid for 24 months.
Decision of RB in 291st meeting	*Registration board deferred the case for submission of following by the firm:* *a. Form-5A indicating details of diluents as the product is in combopack* *b. Accelerated stability data of 06 months.* *c. Stability data covering all the parameters as per finished product specifications.* *d. Finished product specifications as per decision of 267th meeting of Registration Board.* *e. Clarification regarding the difference in limit of each polysaccharide in finished product specifications and stability studies.*
Remarks of Evaluator	The firm has submitted the following documents: i. Revised Form-5A with diluent as combopack. ii. For 100 days Accelerated stability data, the firm submitted that the ICH Q5C: Stability testing of Biotechnology/ Biological Products does not clearly define the requirement for accelerated stability programme. The purpose of 100 days Accelerated stability data at 25^0C is as per VVM14 category of WHO which requires at least 90 days for 25^0C. iii. The firm has submitted 30 months stability data covering all the parameters as per finished product specifications. **iv. In finished product specifications, the firm has demanded British Pharmacopoeia Specifications.** v. The firm has provided the clarification regarding the difference in limit of each polysaccharide in finished product specifications and stability studies that it was a typographical error.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product with BP Specifications subject to compliance of current Import Policy for finished drugs.

3. Correction in composition of already registered veterinary vaccine applied by M/s Vet Line International, Lahore.

M/s Vet Line International, Lahore applied for the correction of composition in registration letter of Avi IB H120 Vaccine as per following details:

Reg. No.	Brand Name	Incorrect Composition on initial Registration Letter	Correct Composition
062006	AVI IB H 120 Vaccine	Each dose contains: Infectious bronchitis virus (IBV), H-120 strain.....**min $10^{3.5}$TCID$_{50}$**	Each dose contains: Infectious bronchitis virus (IBV), **Massachusetts** (H-120) strain……..**min $10^{3.3}$EID$_{50}$**

The firm submitted that they have typographic error in already submitted dossier of Avi IB H120. The firm submitted the following documents:

a. Application with fee challan of Rs. 5000/-
b. Original valid legalized Free Sale certificate indicating new composition
c. Copy of Free Sale submitted with initial dossier at the time of registration indicating previous composition as per registration letter
d. Copy of initial registration letter dated 07-01-2010
e. Copy of last renewal submission dated 28-10-2014
f. Revised Form-5A indicating new composition

RRR section has verified the last renewal submission of product. Moreover, the initial registration letter was issued as per composition mentioned in initially submitted FSC and the composition has been changed in newly submitted FSC and the firm is requesting correction of composition as per new FSC. Furthermore, Registration Board in its 283rd meeting decided as follows:

"Correction/Changes That Necessitate Submission of New Application (Local Manufacture/Import):

a) Change in the dose and/or strength of one or more APIs.
b) Change from an immediate release product to an extended or delayed-release dosage form or vice versa.
c) Change in dosage form.
d) Case of additional flavor.
e) Change of the API to a different API.
f) Inclusion of an additional API in a multicomponent product.
*g) Removal of one API from a multicomponent product."***(F/A)**

As per the decision of Registration Board the said correction requires new application, therefore, the firm has submitted new application on Form-5A with full fee as per following details:

Name of Importer	**M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.**
DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
Name of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
Brand Name +Dosage Form + Strength	Avi IB H120
Composition	Each dose contains:

	Infectious Bronchitis Virus (IBV), Massachusetts (H120) strain……. min. $10^{3.3}$ EID_{50}
Finished product specifications	Ph. Eur. Spec.
Pharmacological Group	Veterinary Vaccine
Shelf life	24 months (2^0C -8^0C)
International availability	Egypt, Indonesia, Moldova etc.
Type of Form	Form-5A
Dy No & Date of application,	Dy. No. 15937 Dated 28-08-2019
Fee submitted	Rs. 100000/- Dated 28-08-2019
Demanded Price / Pack size	1000 Doses/ De-controlled
General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-5/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary

Decision: Registration Board approved the above mentioned correction in composition of Avi IB H120 (Reg. No. 062006) as per valid legalized Free Sale Certificate.

4. Registration of Imported Human Biological applied by M/s Vikor Enterprises (Pvt.) Ltd., Karachi approved in 293rd meeting of Registration Board.

Following product of M/s Vikor Enterprises (Pvt.) Ltd., Karachi was approved in 293rd meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Document Details/ Pack Size	Decision of RB in 293rd meeting
M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet Mandal, Medchal District-500 078, Telangana, India	Typbar TCV Typhoid Vi Conjugate Vaccine Each dose of 0.5mL contains: Purified Vi Capsular Polysaccharide of *Salmonella typhi Ty2* conjugated to Tetanus Toxoid... ….25µg	Legalized CoPP No. 8735/STORES/2019 dated 11-01-2019 valid upto 15-04-2020. 1's Vial (0.5mL)/ Not Provided.	*Keeping in view the above discussion, WHO Prequalification and valid legalized CoPP indicating product availability in country of origin; Registration Board cancelled the approval of Typbar TCV from the name of M/s Sind Medical Store, Karachi granted in 284th meeting and granted approval in name of M/s Vikor Enterprises (Pvt.) Ltd., Karachi as per current Import Policy for Finished Drugs. The Registration letter shall be issued after confirmation of cold storage facility of by the area FID and price verification from Pricing Division.*

Initially, the product was approved in 284th meeting of Registration Board in name of M/s Sind Medical Store, Karachi wherein the Board decided as follows:

"Keeping in view the WHO Prequalification and valid legalized CoPP indicating the availability of product in country of origin; Registration Board approved the product subject to price fixation by the Federal government and compliance of current Import Policy for finished drugs. The firm will submit new brand name along with NOC from manufacturer abroad and Chairman Registration Board is authorized for issuance of Registration letter."

However, while the product was approved in name of M/s Vikor Enterprises (PVt.) Ltd., Karachi, the scenario of brand name was not discussed. The product has already been referred to Pricing Division for price fixation. In this context, it is submitted that M/s Vikor Enterprises (Pvt.) Ltd., Karachi has informed that the brand name

change is not possible as M/s Bharat Biotech International Ltd., India is the originator of this product and Typbar TCV is their brand name which is internationally recognized, even it is WHO Preferred vaccine (with the same name) and till to date this product is not available with any other name globally, so that would not be possible for their principal to give new name for them.
The case was discussed in 295th meeting of Registration Board wherein the Board deferred the case for further deliberation in next meeting.
Accordingly, the case is placed for deliberation of the Board please.

Decision: Registration Board deliberated that already registered brand name is Typbar which is polysaccharide vaccine. While the said vaccine is conjugated vaccine and has TCV suffix in the brand name, which differentiates it from previously registered brand name. Moreover, Typbar TCV is only international brand of Typhoid Conjugate Vaccine and enlisted in WHO Prequalified list with the same name. The Registration Board endorsed its decision of 293rd meeting of Registration Board with Typbar TCV brand name.

5. Change of address of importer for already registered veterinary vaccines applied by M/s Vety-Care (Pvt.) Ltd., Islamabad.

M/s Vety-Care (Pvt.) Ltd., Islamabad has applied for the change in address of importer of already registered veterinary vaccines as per following details:

Sr. No.	Reg. No. & Date of Reg.	Name of product	Date of PRV approval	Last Renewal	Previous Address of Importer	New Address of Importer
1.	004553 27-04-1994	Nobilis Gumboro D78	06-11-1997	10-02-2015	Plot # 81-B, Street # 06, I-10/3, Islamabad	Plot No. 77, Street No. 6, I-10/3, Islamabad
2.	008340 27-04-1994	Nobilis AE 1143	06-11-1997	10-02-2015		
3.	008343 27-04-1994	Nobilis ILT	06-11-1997	10-02-2015		
4.	009626 27-04-1994	Nobilis ND Clone 30	06-11-1997	10-02-2015		
5.	009627 27-04-1994	Nobilis IB+G+ND	06-11-1997	10-02-2015		
6.	010737 27-04-1994	Nobilis REO+IB+G+ND	06-11-1997	10-02-2015		
7.	010738 27-04-1994	Nobilis IB+ND	06-11-1997	10-02-2015		
8.	010739 27-04-1994	Nobilis IB+ND+EDS	06-11-1997	10-02-2015		
9.	012884 29-08-1994	Nobilis Coryza	06-11-1997	10-02-2015		
10.	013232 27-04-1994	Nobilis MA5+ Clone 30	06-11-1997	10-02-2015		
11.	013233 27-04-1994	Nobilis IB MA5	06-11-1997	10-02-2015		
12.	014157 27-04-1994	Nobilis ND Broiler	06-11-1997	10-02-2015		
13.	014158 27-04-1994	Nobilis REO Inac	06-11-1997	10-02-2015		
14.	014159 27-04-1994	Nobilis G+ND	06-11-1997	10-02-2015		
15.	014160	Nobilis EDS	06-11-1997	10-02-2015		

	27-04-1994					
16.	016251 09-01-1995	Nobilis Reo 1133	06-11-1997	10-02-2015		
17.	016252 09-01-1995	Nobilis Gumboro Inac	06-11-1997	10-02-2015		
18.	016255 19-01-1995	Nobilis AE+POX	06-11-1997	10-02-2015		
19.	016257 19-01-1995	Nobilis Gumboro 228E	06-11-1997	10-02-2015		
20.	016259 19-01-1995	Nobilis Newcavac 0.25	06-11-1997	10-02-2015		

The firm has submitted the following documents for each product:

a. Fee challan of Rs. 5000 for each product
b. Copy of valid Drug Sale License No. 156ICT/2013 dated 31-12-2014 valid till 30-12-2020 indicating same proprietor as of previous DSL.
c. Copies of initial registration letter
d. Copies of last renewal submission

The last renewal applications of above products are provided by RRR Section.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Vety-Care (Pvt.) Ltd., Plot # 81-B, Street # 06, I-10/3, Islamabad to M/s Vety-Care (Pvt.) Ltd., Plot No. 77, Street No. 6, I-10/3, Islamabad for above products subject to storage facility verification report of new address.

6. Change in manufacturing site of already registered human biological applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited, Karachi applied for the change in manufacturing site of powder of their already registered product as per following details;

Reg. No.	**Name of Product**	**Already Approved site**	**Newly Applied Site**
083176	Thymoglobuline (Powder for concentrate for solution for infusion)	M/s Genzyme Polycolonals S.A.S., 23 boulevard Chambaud de la Bruyere, 69007 Lyon, France	M/s Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeadon Road, Waterford, Ireland.

The firm has submitted the following documents as per SOPs formulated in 283rd meeting revised in 292nd meeting of Registration Board:

Sr. No.	**SOPs formulated in 283rd Meeting revised in 292nd meeting**	**Documents submitted by the firm**
1.	Application on Form-5F	Provided.
2.	Required fee as per relevant SRO.	Fee Challan of Rs. 100000/-
3.	Copy of registration letter and last renewal status.	Copy of initial registration letter dated 23-01-2017
4.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized CoPP dated 27-03-2019 indicating new manufacturing site issued by HPRA, Ireland.
5.	Site master file of new manufacturing site in case of change of manufacturing site/ source.	Provided.
6.	Revised Sole Agency Agreement when there is change in MAH.	Not Applicable as MAH is not changed.
7.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where	Copy Provided.

	the manufacturer and product license holder are different entities.	
8.	Undertaking that provided information/ documents are true & correct.	Provided.

Decision: Keeping in view the valid legalized CoPP indicating new manufacturing site & approval of HPRA, Ireland (Reference Regulatory Authority); Registration Board approved the change in manufacturing site of Thymoglobuline (Powder for concentrate for solution for infusion) (Reg. No. 083176) from M/s Genzyme Polycolonals S.A.S., 23 boulevard Chambaud de la Bruyere, 69007 Lyon, France to M/s Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeadon Road, Waterford, Ireland as per current Import Policy for finished drugs.

7. Change in Product License Holder of already registered human biological Myozyme (Reg. No.088667) applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited, Karachi applied for the change in Product License Holder of already registered human biological as per following details:

Reg. No.	Name of Product	Already Approved Product License Holder	Newly Applied Product License Holder
088667	Myozyme Powder for concentrate for solution for infusion	M/s Genzyme Europe B.V., Gooimeer 10, NL-1411 DD Naarden, The Netherlands	M/s Genzyme Europe B.V., Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands.

The firm has submitted the following documents as per SOP approved in 283rd meeting Registration Board for the said change:

Sr. #.	Required Documents As per SOP	Documents submitted by the firm
1.	Application on Form-5A with required fee as per relevant SRO.	Provided
2.	Copy of registration letter and last renewal status.	• Copy of initial registration letter dated 10-10-2018 is provided.
3.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name Or Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin Or any legalized document of concerned regulatory authority confirming change of name of Manufacturer/ Marketing Authorization Holder without change in manufacturing site.	Original Legalized CoPP 21/19/140562 dated 02-12-2019 issued by EMA indicating new address of product license holder.
4.	Site master file of new manufacturing site in case of change of manufacturing site/ source.	Not Applicable
5.	Revised Sole Agency Agreement when there is change in MAH.	Provided.
6.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Not applicable as both are same entities.
7.	Undertaking that the provided information/ documents are true/ correct.	Undertaking on the company letter head is provided.

Registration Board in its 292nd meeting discussed the requirement of Form-5F for Post Registration Variations. Registration Board exempted the requirement of Form-5F for change in name of Product License Holder as it may not incur any quality change. However, for change in address of Product License Holder requirement of

Form-5F was not discussed. As the change in address of Product license Holder also does not incur any quality change, hence the requirement of Form-5F in instant case may also be exempted.

Decision: Keeping in view the valid legalized CoPP indicating new Product License Holder & approval of EMA (Reference Regulatory Authority); Registration Board approved the change in Product License Holder of Myozyme Powder for concentrate for solution for infusion (Reg. No. 088667) from M/s Genzyme Europe B.V., Gooimeer 10, NL-1411 DD Naarden, The Netherlands to M/s Genzyme Europe B.V., Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands.

8. Application for separate registration numbers applied M/s Popular International Pvt. Ltd., Karachi available in the market under same number.

Following application of M/s Popular International Pvt. Ltd., Karachi for the change in name of Product License Holder and Manufacturer of registered human biologicals was discussed by Registration Board in its 293rd meeting:

Sr. No.	Reg. No. & Date	Date of Last renewal submission	Name of Product	Already Approved Name of Manufacturer	Newly Applied Name of Manufacturer
1.	077515 23-09-2013	18-09-2018	Gamunex-C 10%	M/s Grifols Therapeutics Inc. 8368 US 70 Business Hwy West, Clayton, NC 27520, US	M/s Grifols Therapeutics LLC 8368 US 70 Business Hwy West, Clayton, NC 27520, US
2.	012835 29-10-1991	15-05-2018	Hyperhep B S/D		
3.	007965 07-02-1985	15-05-2018	Koate-DVI		
4.	007967 07-02-1985	15-05-2018	Plasbumin-20 100ml		
5.	007967 07-02-1985	15-05-2018	Plasbumin-20 50ml		
6.	007967 07-02-1985	15-05-2018	Plasbumin-25 100ml		
7.	007967 07-02-1985	15-05-2018	Plasbumin-25 500ml		

The Board after discussion decided as follows:

"Keeping in view the valid legalized CoPP and approval of USFDA (Reference Regulatory Authority), Registration Board approved the change in name of product license holder and manufacturer from M/s Grifols Therapeutics Inc. to M/s Grifols Therapeutics LLC for above products. Registration Board further advised the firm to submit separate applications with full fee for products at sr. no. 5 to 7 for grant of separate registration numbers."

Accordingly, the firm has now submitted the applications on Form-5A with Fee challans of Rs. 50000/- each for all products as per following details:

Sr. No.	Product License Holder and Manufacturer	Brand Name and Composition	CoPP details	Type of Form Dy. No. Date of Application Pack Size
1.	**Product License Holder:** Grifols Therapeutics LLC, 79 T.W. Alexander Dr., 4101 Research Commons,	**Plasbumin-20; Intravenous** Each 50ml contains: Albumin…..10gm Shelf Life: 36 months (≤30^{0}C)	Legalized CoPP No. ZFM3-JHME WHO dated 10-01-2019 valid till 09-01-2021 issue by USFDA.	Form-5A Dy. No. 4998 Date: 19-03-2020 Rs. 50000/- Date: 19-03-2020

	Research Triangle Park, NC 27709, US **Manufacturer:** M/s Grifols Therapeutics LLC,			1's Vial (50mL)/ As per DPC
2.	8368 US 70 Bus Hwy W, Clayton, NC 27520, US, License # 1871	**Plasbumin-25; Intravenous** Each 50ml contains: Albumin…..12.5gm Shelf Life: 36 months (≤30^{0}C)	Legalized CoPP No. 5ZTP-V263 WHO dated 10-01-2019 valid till 09-01-2021 issue by USFDA.	Form-5A Dy. No. 4998 Date: 19-03-2020 Rs. 50000/- Date: 19-03-2020 1's Vial (50mL)/ As per DPC
3.		**Plasbumin-25; Intravenous** Each 100ml contains: Albumin…..25gm Shelf Life: 36 months (≤30^{0}C)	Legalized CoPP No. 5ZTP-V263 WHO dated 10-01-2019 valid till 09-01-2021 issue by USFDA.	Form-5A Dy. No. 4998 Date: 19-03-2020 Rs. 50000/- Date: 19-03-2020 1's Vial (100mL)/ As per DPC

Decision: Registration Board advised DBER to issue Post Registration variation approval granting three separate registration numbers for Plasbumin-20 (50mL), Plasbumin-25 (50mL) & Plasbumin-25 (100mL).

9. Withdrawal of license of Shan TT 5ml Adsorbed Tetanus Vaccine (Reg. No. 079273) applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pkaistan Limited, Karachi applied for the cancellation of registration of following registered human biological:

Reg. No. & Date of Reg.	Name of Manufacturer	Brand Name & Composition	Pack Size
079273	M/s Shantha Biotechnics Private Limited, Survey No. 274, Athvelli village, Medchal Mandal – 501401, Ranga Reddy district, Telangana, India	Shan TT (Adsorbed Tetanus Vaccine) Each dose of 0.5ml contains: Tetanus Toxoid……≥40IU	5ml/10 dose vial

The firm submitted that this decision is not based on quality, safety or efficacy issues but has been taken for following reason:

i. WHO and UNICEF recommends replacing TT vaccine with Td vaccine
ii. No demand for TT vaccine has been received since January, 2019 in national and International immunization programs.
iii. The Tetanus containing vaccine market is healthy market, with ample capacity.
iv. Sanofi has also applied for delisting of Shan TT from the WHO prequalified vaccine list. Shan TT will be kept in the WHO list until the last lot expired in September, 2020.

The firm has also submitted the copy of delisting letter issued by WHO.

Decision: Registration Board did not accede to request of the firm and advised to make it available for market supply.

10. Application for Exemption of registration number & MRP on Pakistan specific packs at the time of import and permission for local priniting of same applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited has requested for the exemption of Registration Number & MRP at the time of import on Pakistan Specific packs of below mentioned human biologicals:

Sr. No.	Reg. No.	Name of Product	Pack Size
1.	052293	Apidra Solostar Solution for Injection	3ml x 5PFS
2.	017004	Clexane Injection 40mg	2 Syringes (0.4mL)
3.	017809	Clexane Injection 60mg	2 Syringes (0.6mL)
4.	017810	Clexane Injection 80mg	2 Syringes (0.8mL)
5.	052294	Lantus Solostar Solution for Injection	3ml x 5PFS
6.	031388	Lantus Solution for Injection	10ml x 1's Vial
7.	090645	Toujeo 300Units/ml (Insulin Glargine)	3/s Pre-filled Pens
8.	069588	Enterogermina oral suspension 2 Billion	10's , 20's
9.	095289	Enterogermina oral suspension 4 Billion	5ml x 10 Vials, 5ml x 20 Vials

The firm has submitted the following documents:

1. Application with fee challan of Rs. 5000/- for each product
2. SOPs for control of repacking operations.
3. An undertaking that we will print the Registration Number and Maximum Retail Price (MRP) on each pack of above products at our Karachi site bearing DML No. 000007, before releasing the goods into the market.

The firm further submitted that:

"COVID 19 pandemic has brought the world to its knees. Even the countries supposed to have a strong healthcare system are unable to meet the requirements during these crucial times. Moreover, due to current work situation in majority of the countries affected many of the usual tasks have become a challenge to fulfill. Sanofi Aventis Pakistan Limited has always ensured to find ways to continue serving patients of Pakistan. Unfortunately, COVID -19 has been serious concern for whole of the world but still Sanofi embraces the challenge to serve patients at any cost.

Keeping in view the current scenario, we Sanofi-Aventis Pakistan Limited, Karachi would like to request the competent authority for exemption from Registration Number and Maximum Retail Price on Pakistan Specific packs and allow us to locally print Registration Number and MRP after import at our registered premises located at Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi."

Decision: Registration Board acceded to the request of the firm for import of Apidra Solostar (3ml x 5PFS) (Reg. No. 052293), Clexane Injection 40mg (2 Syringes(0.4mL) (Reg. No. 017004), Clexane Injection 60mg (2 Syringes(0.6mL) (Reg. No. 017809), Clexane Injection 80mg (2 Syringes(0.8mL) (Reg. No. 017810), Lantus Solostar (3ml x 5PFS) (Reg. No. 0052294), Lantus Solution for Injection (10ml x 1's Vial) (Reg. No. 031388), Toujeo 300Units/mL (3's Pre-filled Pens) (Reg. No. 090645), Enterogermina oral suspension 2 Billion (10's & 20's) (Reg. No. 069588), Enterogermina oral suspension 4 Billion (5ml x 10 Vials, 5ml x 20 Vials) (Reg. No. 095289) in Pakistan Specific Packs. The Board advised the firm to locally print MRP and Registration Number and other parameters as per Drugs (Labelling & Packing) Rules, 1978 before sale of drug at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial area, Karachi to comply the requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for six (06) months only. The firm shall submit the future plan regarding the import of products in compliance with Drugs (Labelling & Packing) Rules, 1986.

Evaluator: AD-I

11. Imported Veterinary Biological applied by M/s Forward Solutions, Lahore deferred in 292nd meeting of Registration Board.

Following product of M/s Forward Solutions, Lahore was deferred in 258th meeting of Reg. Board held on 25-26thApril, 2016*for clarification by the firm for non-availability of the formulation by the regulatory authority in the country of the origin.* The case was taken in expert working group and the recommendations were considered in 292nd meeting of Registration Board held on 1st to 2nd October, 2019wherein the Board decided as under:

Product License Holder and Manufacturer	**Brand Name and Composition**	**CoPP details/ Shelf life/ pack size**	**Decision of 292nd RB meeting**
Product License Holder: FATRO S.p.A – Via Emilia, 285–40064-Ozzano Emilia (Bologna) Italy. **Dosage Form Manufacturer:** FATRO S.p.A–Via Molino Emili, 2–25030-Maclodio (BS)- Italy.	**IBA-VAC ST** Freeze-dried vaccine for administration in drinking water for chickens) Each dose contains: Live moderately attenuated virus, intermediate plus, of Infective Bursitis (Gumboro disease), Winterfield strain 2512: min. 10^2– max. 10^3EID_{50}	Legalized CoPP No. N. 25/2020/C dated 11th February 2020. 18 Months (2°C—8°C) 2500doses	*a. Reason for non-availability of the products in the country of origin by their concerned Regulatory Authority.* *b. Evidence of availability of the same products in any other reference regulatory authority as prescribed by the Registration Board.* *c. Evidence of availability of the same products with other brand*

			names in country of origin or in any other reference regulatory.

It is submitted that the firm was asked to clarify above mentioned queries for which the firm has submitted fresh Legalized CoPP details of which are mentioned above. The CoPP reflects that the product is in free sale in country of origin.

Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

12. Request for approval of label update by M/s Eli Lilly Pakistan (Private) Limited for Trulicity 0.75mg/0.5mL & 1.5mg/0.5mL injections:

M/s Eli Lilly Pakistan (Private) Limited has applied for change in label of their already registered products as per following details:

Name of products	Current Leaflet (Indication)	New Leaflet (indication)
1. Trulicity 0.75mg/0.5mL injection (Reg. No. 088524) **2. Trulicity 1.5mg/0.5mL injection (Reg. No.** 088525)	Trulicity is indicated in adults with type 2 diabetes mellitus to improve glycaemic control as: *Monotherapy* When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. *Add-on therapy* In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 5.1 for data with respect to different combinations).	<u>Type 2 Diabetes Mellitus</u> Trulicity is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications • In addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and **cardiovascular events**, and the populations studied, see sections 4.4, 4.5 and 5.1.
	4.4 Special warnings and precautions for use Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. This should be considered when treating patients with impaired renal function since these events, i.e. nausea, vomiting, and/or diarrhoea, may cause dehydration	**4.4 Special warnings and precautions for use** Dehydration, sometimes leading to acute renal failure or worsening renal impairment, has been reported in patients treated with dulaglutide, especially at the initiation of treatment. Many of the reported adverse renal events occurred in patients who had experienced nausea, vomiting, diarrhoea, or dehydration.

	which could cause a deterioration of renal function.	Patients treated with dulaglutide should be advised of the potential risk of dehydration, particularly in relation to gastrointestinal side-effects and take precautions to avoid fluid depletion. **4.8. Undesirable effects** **Dehydration (Uncommon)**

The firm has submitted following documents for the said change;

i. Fee of 20,000/- (Rs. 5000/- for each product for applied (2) changes)
ii. Copy of Reg. Letters
iii. Copy of existing leaflet
iv. Copy of updated leaflet
v. Justification of change.
vi. Copy of EMA approvals

It is submitted that the said update has been checked online for desired updates and changes were mentioned in new leaflet.

Decision: Keeping in view the approval of EMA (Reference Regulatory Authority); Registration Board approved the above mentioned indications for Trulicity 0.75mg/0.5mL (Reg. No. 088524) & Trulicity 1.5mg/0.5mL (Reg. No. 088525)

13. Registration of Veterinary Biological products applied by M/s Forward Solutions (Animal Health Company) deferred in 291st meeting of Registration Board.

Following products of M/s Forward Solutions, Lahore were deferred in291st meeting of Registration Board held on 2-4th September 2019. The details are as under;

1.	**Name of Importer**	M/s Forward Solutions (Animal Health Company) Plot No.19-B, Off Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore-Pakistan
	DSL details	DSL No. 05-352-0066-028137D valid till 10 Feb 2020
	Name of Manufacturer	**ATAFEN** Ata Fen VeterinerMalzemeleriHayvancilik Paz. San. Ve Tic. A.S. OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey
	Brand Name +Dosage Form + Strength	**VBR COLI SERA + C COMBINED SERUM ANTIBODY**
	Composition	Active Substance: Each 1 ml of vaccine contains: *Escherichia coli* K99antibodies …….…….. ≥ 1/640 AU *Clostridium perfringens* Type C antibodies……≥ 50 IU
	Finished product specifications	As per innovator
	Pharmacological Group	Veterinary Biologicals (Antibody Serum)
	Shelf life	24 Months (Store at 2°C -8°C)
	International availability	Turkey, Azerbaijan.

	Products already registered in Pakistan	N/A
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.1377/AD(BD) dated 3rdDecember, 2018 30thNov, 2018 Fee Submitted: Rs.100,000/-
	Demanded Price / Pack size	Decontrolled/ 50mL(20 doses)
	General documentation	• Legalized Free Sale Certificate issued by Ministry of Agriculture and Forestry, General Directorate of Food and Control, Turkey. • Legalized GMP Certificate having Certificate No.GMP/TR/V/Yi/S0123/2018 issued by Ministry of Agriculture and Forestry General Directorate of Food and Control, Turkey valid till 22nd November 2020.
	Decision of 291st meeting of Registration board	Registration Board deferred the case for submission of following by the firm: a. Valid legalized GMP and Free Sale Certificates. b. Stability studies data of commercial batches **c.** Clarification regarding two manufacturing sites mention on GMP.
2.	**Name of Importer**	M/s Forward Solutions (Animal Health Company) Plot No.19-B, Off Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore-Pakistan
	DSL details	DSL No. 05-352-0066-028137D valid till 10 Feb 2020
	Name of Manufacturer	**ATAFEN** Ata Fen VeterinerMalzemeleriHayvancilik Paz. San. Ve Tic. A.S. OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey
	Brand Name +Dosage Form + Strength	**VBR COLIMIX 9** Combined *Clostridium novyi* Type A, *Clostridium septicum*, *Clostridium sordelli*, *Clostridium perfringerns* Type B, C, D, *Clostridium chauvoei*, *Clostridium haemolyticum* and *Escherichia coli* Bacterin & Toxoid.
	Composition	<u>Active Ingredient:</u> 2ml of the vaccine provide 75% minimum immune response against Clostridum haemolyticum antigen in guinea pigs, > 1.0 IU / ml Clostridium soredellii, > 10.0 IU / ml Clostridium perfringens Type B and Type C Beta Antitoxin, > 5.0 IU / ml Clostridium perfringens Type D Epsilon Antitoxin, > 3.5 IU / ml Clostridium novyii Alfa Antitoxin, > 2.5 IU / ml Clostridium septicum Alfa Antotoxin, it provides 90% minimum immune response against Clostridium chauvoei antigen in guinea pigs, > 100 AU minimum immune response against Escherichia coli antigen K99/F41/F17(Fy),
	Finished product specifications	As per innovator

	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 Months [2 Years] (Store at 2°C -8°C)
	International availability	Turkey, Azerbaijan.
	Products already registered in Pakistan	N/A
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.1377/AD(BD) dated 3rdDecember, 2018 30thNov, 2018 Fee Submitted: Rs.100,000/-
	Demanded Price / Pack size	Decontrolled/ 30mL 250 ml vial (62 cattle dose or 125 sheep and goats dose) / decontrolled
	General documentation	• Legalized Free Sale Certificate issued by Ministry of Agriculture and Forestry, General Directorate of Food and Control, Turkey. • Legalized GMP Certificate having Certificate No.GMP/TR/V/Yi/S0123/2018 issued by Ministry of Agriculture and Forestry General Directorate of Food and Control, Turkey valid till 22nd November 2020.
	Decision of 291st meeting of Registration board	Registration Board deferred the case for submission of following by the firm: a. Valid legalized GMP certificate. b. Notarized English translation of Free Sale Certificate. c. Stability studies data of commercial batches. d. Clarification regarding two manufacturing sites mention on GMP.

In the above context, the documents required as per decision of Registration Board and documents submitted by the firm are summarized as under;

Sr. No.	**Documents required as per 291st RB decision**	**Documents/ Clarification submitted by the firm**	
		Name of Product	
		VBR COLI SERA + C COMBINED SERUM ANTIBODY	**VBR COLIMIX 9**
1.	Valid legalized GMP certificate.	Legalized GMP No. Certificate No. GMP/TR/V/YI/S0123/2018	Legalized GMP No. Certificate No. GMP/TR/V/YI/S0123/2018
2.	Notarized English translation of Free Sale Certificate.	Notarized English translated Free Sale Certificate submitted. However, composition and pack size are not mentioned in the FSC.	Notarized English translated Free Sale Certificate submitted. However, composition and pack size are not mentioned in the FSC
3.	Stability studies data of commercial batches.	Submitted	Submitted
4.	Clarification regarding two manufacturing sites mention on GMP.	Atafen do not have two manufacturing sites. **Name of Manufacturer** **Address of Manufacturer** Ata Fen Veteriner OSB Mah. 21 Malz Sokak No.7/A	Atafen do not have two manufacturing sites. **Name of Manufacturer** **Address of Manufacturer** Ata Fen Veteriner OSB Mah. 21 Malz Sokak No.7/A

		Hay Paz. San. Ve Tic. A.S. Ulucak Kemalpasa/ IZMIR	Hay Paz. San. Ve Tic. A.S. Ulucak Kemalpasa/ IZMIR

Remarks of Evaluator:

1. The firm has changed pack size details;

Previous Pack Size		**New Pack Size**	
VBR COLI SERA + C COMBINED SERUM ANTIBODY	**VBR COLIMIX 9**	**VBR COLI SERA + C COMBINED SERUM ANTIBODY**	**VBR COLIMIX 9**
100 ml vial	250 ml vial	50mL(20 doses) vial	30mL vial

The firm has submitted revised form 5A.

2. The Free Sale Certificate does not mention composition and pack size. The firm has submitted undertaking that they will submit the required FSC mentioning composition and pack size before registration.

3. The stability data has been provided for complete shelf life with time intervals of 0,4,8,12,16,20,24 months which compiles to the specifications. Accelerated stability data has also been submitted.

Decision:

Registration Board deferred the products for submission of following by the firm:

a. Valid Legalized Free Sale certificate indicating composition & desired pack sizes.
b. Scientific immunological relevance of Clostridium species in Pakistan.

14. Basagine Injection approved in 256th meeting of Registration Board applied by M/s Getz Pharma (Pvt.) Limited, Karachi.

Following product of M/s Getz Pharma (Pvt.) Limited, Karachi was approved in 257th meeting of Registration Board as per following details:

Name of Manufacturer	**Brand Name & Composition as per CoPP**	**Decision of RB in 257th meeting**
M/s Gan & Lee Pharmaceuticals Ltd., No.8,JingshengNorth 3rdStreet, Golden Bridge Science Industrial Base, Zhongguancun Science Park, Tongzhou District, Beijing, China.	Basagine (Recombinant Insulin glargine injection) Each ml contains; - Recombinant Insulin Glargine…..…..100U	*Approved as per valid Legalized CoPP subject to inspection of manufacturer abroad as per Import Policy for Finished Drugs, verification of storage facilities and fixation of MRP by Pricing Committee.*

It is submitted that as per available record the product is already registered from same source in name of M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi with brand name Basalin Insulin 100IU/3ml cartridge **(Reg. No. 053809)**. M/s Getz Pharma (Pvt.) Ltd., Karachi applied as new application and provided the authorization letter in their name from M/s Gan & Lee Pharmaceuticals Ltd., China.

To confirm status of the product from M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi letter was forwarded on 19th June 2019.The firm was advised to submit response and clarify its position. However, no response was received. The case was taken in 291st meeting of Registration Board held on 2nd, 3rd& 4th September 2019 wherein the board decided as under;

"Registration Board advised DBER to issue a reminder to M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi and to ask DRAP office, Karachi to provide the data of import of Basalin by M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi."

Accordingly, a letter was forwarded to DRAP office, Karachi and a reminder to M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi

It is submitted that reply from DRAP office, Karachi was received wherein it was informed that the product has not been imported through this office since January 2018 to date, as per available record. Moreover, no reply was received from East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi. So, the matter was again taken in 295th meeting of Reg. Board wherein board decided as under;

Registration Board advised DBER to issue final letter to M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi and advise them to appear before Registration Board in forth coming meeting for personal hearing to explain their position regarding the authorization of their product Basalin in name of M/s Getz Pharma (Pvt.) Limited, Karachi by their principal M/s Gan & Lee Pharmaceuticals Ltd., China. If M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi failed to attend the meeting, Registration Board will make ex-party decision & shall grant the registration in name of M/s Getz Pharma (Pvt.) Limited, Karachi.

Accordingly, a letter has been issued on 19-08-2020 to ask them to appear before Registration Board. In response, the firm has submitted that they are unable to attend the meeting due to current conditions in Karachi.

Decision: Registration Board advised DBER to issue show cause letter to M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi to give them final opportunity to appear before Registration Board in forth coming meeting for personal hearing under section 42 of the Drugs Act, 1976 read with rule 24 (17) of the Drugs (Licensing, Registering, Advertising) Rules, 1976 to explain their position regarding the authorization of their product Basalin in name of M/s Getz Pharma (Pvt.) Limited, Karachi by their principal M/s Gan & Lee Pharmaceuticals Ltd., China. If M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi failed to avail this final opportunity, Registration Board will make ex-party decision and shall grant the registration in name of M/s Getz Pharma (Pvt.) Limited, Karachi.

15. Change of address for importer on registration letter of MMR Vaccine (Reg. No. 013272):

M/s Amson Vaccine & Pharma has applied for change of address on approval letter of transfer of registered products of **MMR Vaccine (Reg. No. 013272):**

Reg No	Brand Name of Product	Manufacturer	Address of importer on Reg. Letter	Applied / desired address of importer
013272	Measles, Mumps, Rubella Vaccine live, attenuated (freeze-dried) M.M.R	Serum Institute of India Pvt Ltd(710286), 212/2, Hadapsar, Pune, 411028, Dist – Pune Zone3 India.	**M/s. Amson Vaccines & Pharma (Pvt.) Ltd** 154, Industrial Triangle, Kahuta Road, Islamabad	**M/s. Amson Vaccines & Pharma (Pvt.) Ltd** 115, Industrial Triangle, Kahuta Road, Islamabad

The firm has submitted;

i. Fee Rs. 5030/-
ii. Copy of registration letter and renewal (which has beensubmitted within time)

It is pertinent to mention that in DSL, mentioned address is "*115, Industrial Triangle, Kahuta Road, Islamabad"* and cold storage facility report is also available for the same address.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s. Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabad to M/s. Amson Vaccines & Pharma (Pvt.) Ltd., 115, Industrial Triangle, Kahuta Road, Islamabad for above product subject to storage facility verification report of new address.

16. Local Human Biological applied by M/s BF Biosciences, Lahore, deferred in 295th meeting of Registration Board.

Following human biological products applied by M/s BF Biosciences Ltd, Lahore were deferred in 295th meeting of Reg. Board. The details of the case are as under;

1.	**Name of Manufacturer/ Applicant**	M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore Bulk Manufacturer (Product License Holder in CoPP): M/s GEMABIOTECH S.A.U Fray Justo Sarmiento 2350 – 5ºPisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina.
	Brand Name +Dosage Form + Strength	Eterna 25mg Injection
	Composition	Each ml contains: Each PFS contains Etanercept…. 25mg/0.5mL
	Finished product specifications	As per innovator
	Approval status in Reference countries	Enbrel
	Products already registered in Pakistan	Enbrel (M/s Pfizer)
	Shelf life	24 months
	Type of Form Dy No & Date of application, Fee submitted	Form-5 1379(R&I) 24-11-2016 Rs. 20000/- dated 23-11-2016
	Demanded Price/ Pack size	1's PFS/ As per SRO
	General documentation	DML No. 000655 dated 30-01-2019 GMP inspection report dated 24-12-2018
2.	**Name of Manufacturer/ Applicant**	M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore Bulk Manufacturer (Product License Holder in CoPP): M/s GEMABIOTECH S.A.U Fray Justo Sarmiento 2350 – 5ºPisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina.
	Brand Name +Dosage Form + Strength	Eterna 50mg Injection
	Composition	Each ml contains: Each PFS contains Etanercept…. 50mg/0.5mL
	Finished product specifications	As per innovator
	Approval status in Reference countries	Approved
	Products already registered in Pakistan	Enbrel (M/s Pfizer)
	Shelf life	24 months

	Type of Form Dy No & Date of application, Fee submitted	Form-5 1379(R&I) 24-11-2016 Rs. 20000/- dated 23-11-2016
	Demanded Price/ Pack size	1's PFS/ As per SRO
	General documentation	DML No. 000655 dated 30-01-2014 GMP inspection report dated 22-02-2016

The firm has submitted the documents/data in the light of regulatory guideline for biological products approved in 278th meeting of Registration Board as per following details:

Sr. No.	Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	Documents submitted by firm
1.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP certificate No. 20132021-000 013-18 dated 19-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque TecologicoLitoral, of the Province of Santa Fe, of the Argentine.
2.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	The firm has provided legalized copy of CoPP from ANMAT (National Administration of Drugs, Foods and Medical Devices) which is signed electronically.
3.	The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Details are included below.
4.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (Not applicable).
5.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Provided
6.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same), visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application.	The firm has submitted stability study data and CoA wherein the tests conducted are as under; i. Appearance ii. Leak test iii. pH iv. Extractable volume v. Immuno characterization vi. Potency vii. Sterility viii. Bacterial endotoxins ix. Particulate matter. x. Sialic acid content xi. Protein concentration xii. Peptide mapping xiii. Identification (by SDS page) xiv. Isoforms content xv. Dimers and related proteins of higher molecular mass
7.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of	Provided

	DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	
8.	The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided.
9.	The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Not Provided.
10.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Provided.
11.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Provided.

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**Physicochemical Characterization** i. Appearance and pH determination by visual method and potentiometric method. ii. Protein content by Spectroscopy. iii. Osmolarity by Osmometric vapor pressure. iv. Amino acid sequence by UPLC-ESI-MS/MS. v. Molecular Mass determination by MALDI-TOF MS. vi. Peptide mapping by RP-HPLC. vii. Analysis of Secondary & Tertiary structure by circular Dichroism (CD) and Intrinsic Fluorescence. viii. Structure Analysis by NMR. ix. Analysis of free monossacharides, Reversed Phase HPLC. x. Determination of High molecular weight and impurities by SEC-HPLC.
Biological Activity	Determination of Biological Activity by Quantification of the protection activity by inhibition of the cytotoxic effect of TNF-alfa.
Immunochemical properties	Immuno Identification by western blot.
Impurities	Impurities by SEC-HPLC.
Stability Studies	Long term stability data is provided while accelerated stability data is not provided.
Non-clinical Studies i. In-vitro Studies ii. In-vivo Studies	1. In vitro studies include determination of TNF-α binding through the quantification of the protection activity by inhibition of the cytotoxic effect of TNF-α. In addition, TNF-αbinding analysed by ELISA and Surface Plasmon Resonance (SPR). 2. In vitro secondary pharacodynamic comparability assays (ADCC, CDC, TNF-β binding and Fcγ receptors binding) performed and detailed in this module. Studies are performed in *Cebusapella* monkeys and Wistar rats (WKAH/Hok/LAE).
Clinical Studies	**Safety** Open randomized balanced Phase 1, actively – controlled, single dose, crossover study with two treatment periods. Thirty subjects treated with two products i.e. Enerceptan® Gemabiotech S.A. laboratory against Pfizer reference Enbrel® (15 each)

	Efficacy A phase III randomized evaluator blinded, Multicenter, Non-inferiority study to evaluate the comparative Efficacy, Safety and Immunogenicity of Enerceptan® (Gemabiotech) with Enbrel® (Pfizer) in combination with methotrexate in the treatment of patients with rheumatoid arthritis. (138 patients)

Remarks of Evaluator(295th meeting):

ii. The firm has provided legalized copy of CoPP from ANMAT (National Administration of Drugs, Foods and Medical Devices) which is signed electronically. However, the same certificates received earlier used to be manually signed. For this the firm has clarified that the document issuance process has been Digitalized in Argentina since January 2019. The firm also referred to online website of ANMAT which shows that *"depapelization program"* has been launched.

iii. The CoPP submitted by the firm reflects that **GEMABIOTECH S.A.U Fray Justo Farmiento2350 – 5º PisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina**is Product License Holder while **MR Pharma S.A., Etados Unidos 5105, Malvinas Argentinas, Provincia de Beunos Aires, Argentina** is Manufacturer of pharmaceutical form.It is pertinent to mention that GMP certificate submitted by the firm is of manufacturer **ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque TecologicoLitoral , of the Province of Santa Fe, of the Argentine.**

In order to establish the relationship between

a. GEMABIOTECH S.A.U
b. MR Pharma S.A
c. ZELLTEK S.A

The firm has submitted following clarification letter by GEMABIOTECH S.A.U

- *Gemabiotech S.A.U. is a pharmaceutical company and the Marketing Authorization (MA) holder of certain finished dosage forms, registered and located in Argentina.*
- *Zeltek S.A. is an API manufacturing company also registered and located in Argentina that produces some of the APIs of Gemabiotech S.A.U. marketed pharmaceutical products.*
- *The manufacturing process of Gemabiotech S.A.U. finished products is outsourced to a contract manufacturing organization called MR Pharma S.A., which is a thirdparty company registered and located in Argentina too.*
- *Gemabiotech S.A.U. performs the quality control and releases all the finished products to the market after a Quality Assurance final inspection.*
- *There exist a manufacturing contract between Gemabiotech S.A.U. and MR Pharma S.A., ruling the relationship between them and the responsibilities of each party.*
- *The three companies, Zeltek S.A., Gemabiotech S.A.U and MR Pharma S.A., are inspected and approved by A.N.M.A.T, the Argentina Drug Agency, regarding GMP normative compliance.*

The case was discussed in the 295thmeeting of Reg. Board and it was pointed out by the DBER that the firm representative was present in the committee that finalized the Biosimilar evaluation guidelines hence their data should be exemplary. The board decided as under;

> *"Registration Board deferred the case for submission of data of complete test results as mentioned above in section 6 of guidelines approved in 278th meeting of Registration Board and Board advised the DBER that the test not performed by the firm or not required should clearly be mentioned."*

It is submitted that the firm has provided CoAs and result of Abnormal Toxicity Test which were performed by Centre of Excellence in Molecular Biology (CEMB) and are outsourced. Abnormal Toxicity test has been performed for three batches of both products (Eterna 25mg & 50mg) in three mice (for each batch).

Decision: Registration Board referred the case to Committee on Biological Drugs constituted in 273rd meeting of Registration Board for its recommendations on the requirements of toxicity studies and abnormal toxicity studies. Moreover, Registration Board nominated Lt. Gen. (R) Prof. Dr. Karamat Ahmed Karamat (HI-M, SI-M) as Chairman of said committee.

Evaluator: AD-II

17. Imported Human Biologicals applied by M/s Nees International, Lahore deferred in 291st meeting of Registration Board

The following two products are deferred in the 291st meeting of Registration Board. The details of the products are as under;

1.	**Name of Importer**	**M/s Nees International, Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.**
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar
	Name of Manufacturer	**Product License Holder & Manufacturer:** Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gangwon-do, Republic of Korea
	Brand Name +Dosage Form + Strength	BotulaxInj (100 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (100 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------100 units
	Finished product specifications	BP specification
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. (R&I) Dated 6th February 2018 Rs. 100,000/-6th February, 2018
	Demanded Price / Pack size	$60+ 10%FOC /100 units Vial
	General documentation	Legalized CoPP No.2017-A1-2061 dated 16-10-2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017 Copy of distribution Agreement

Decision of 291st meeting of RB: *Registration Board deferred the case for submission of following by the firm:*

a. Evidence of availability of formulation in reference regulatory authorities along with approved indications.

b. *Medical indication of the product as approved by regulatory authority of manufacturer.*

Remarks of Evaluator:

The firm has submitted that the Innovator of their product is Botox which is USFDA approved product and indications of their product will be same as that of Innovator product (i.e. Botox).

The Botox was checked in the USFDA and it was found that active constituent in the Botox is Onabotulinum toxin A while in the applied product active constituent is letibotulinum toxin A. Please note that in FDA two other types botulinum toxin A are also approved with the name of abobotulinum toxin A (Brand Name: DYSPORT) and incobotulinum toxin A (Brand Name: Xeomin) but the letibotulinum toxin A is not present in the online USFDA approval list. Moreover, applied formulation is not available in any reference regulatory authority.

Response of the firm: The firm has submitted the following clarification from the Principal Manufacturer:

We. Hugel Inc., hereby declare that Botulax (USAN: Letibotulinnumtoxin A) and Botox have the similar characteristics in terms of active substance, excipients, non-clinical pharmacodynamics study and comparative clinical studies with Botox as a control drugs. The firm has also informed that it is under registration in many European countries.

2.	**Name of Importer**	**M/s Nees International, Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.**
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar

	Name of Manufacturer	**Product License Holder & Manufacturer:** Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gangwon-do, Republic of Korea
	Brand Name +Dosage Form + Strength	Botulaxinj (50 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (50 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------50 units
	Finished product specifications	**BP specification**
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 5615 (R&I) Dated 11thFebruary 2019 Rs. 100,000/- 7th February, 2019
	Demanded Price / Pack size	$37.5+ 10% FOC/100 units Vial
	General documentation	CoPP No.2017-A1-2062 dated 16th October,2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017 Copy of distribution Agreement

Decision of 291st meeting of RB: Registration Board deferred the case for submission of following by the firm:

a) Evidence of availability of formulation in reference regulatory authorities along with approved indications.
b) Evidence of availability of formulation in Pakistan.
c) Medical indication of the product as approved by regulatory authority of manufacturer.

The firm has submitted that the Innovator of their product is Botox which is USFDA approved product and indications of our product will be same as that of Innovator product (i.e. Botox).

Remarks of Evaluator:

- There is no formulation available in Pakistan in the 50IU.

The Botox was checked in the USFDA and it was found that active constitute in the Botox is Onabotulinum toxinA while in the applied product active constitute is letibotulinum toxinA. Please note that in FDA two other types botulinum toxin A are also approved with the name of abobotulinum toxinA (Brand Name: DYSPORT) and incobotulinum toxinA (Brand Name: Xeomin) but the letibotulinum toxin A is not present in the online USFDA approval list. Moreover, applied formulation is not available in any reference regulatory authority.

Response of the firm: The firm has submitted the following clarification from the Principal Manufacturer ;

We. Hugel Inc., hereby declare that Botulax (USAN: Letibotulinnumtoxin A) and Botox have the similar characteristics in terms of active substance, excipients, non-clinical pharmacodynamics study and comparative clinical studies with Botox as a control drugs. The firm has also informed that it is under registration in many European countries.

Decision: Registration Board deferred and advised applicant to provide data / evidence regarding availability of formulation in any of reference regulatory authorities.

18. Imported Human Biological applied by M/s Medinet Pharmaceuticals, Rawalpindi deferred in 291st meeting of Registration Board.

The following product of M/s Medinet Pharmaceuticals, Rawalpindi was deferred in 291st meeting of Registration Board. The details of the products are as under;

Name and address of Importer	**M/s Medinet Pharmaceuticals, Rawalpindi** **Building No. 601, Lane No. 05, Main Peshawar Road, Rawalpindi**
Detail of Drug Sale License	Drug Sale License No.01-374-0176-022646Ddated 13-12-2017 valid till 13-12-2019
Name of Manufacturer	**Product License Holder & Manufacturer:** Probiomed S.A de C.V. San Esteban No.88, Col. Santo Tomas, C.P. 02020, Deleg, Azcapotzalco, D.F., Mexico.
Brand Name +Dosage Form + Strength	FILATIL Prefilled Syringe 300MCG/1ML (Filgrastim)
Diary No. Date of R& I & fee	Dy. No. 1798 (R&I) dated 21-11-2014 Fee deposited: Rs. 50000/- dated 17-11-2014 + Rs.50000/- dated 15-3-2016
Composition	Each prefilled syringe contains: Filgrastim ……300 mcg
Pharmacological Group	rDNA therapeutic protein
Type of Form	Form 5-A
Finished Product Specification	BP specification
Shelf Life	2 years
Document Details	Legalized GMP Certificate No. 183300516A0174 dated 20-03-2018 valid until 2-06-2019. Legalized Free sale certificate No. 183300CI170155 dated 23-04-2018 with one year of validity and copy of translation notarized by Notary Public.
Pack size & Demanded Price	1's PFS/Not Provided.
International Availability	Neupogen of M/s Amgen Limited, UK
Products already registered in Pakistan	Neupogen
The detail of biosimilarity data submitted by the firm as under:	

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison Physicochemical Characterization	a) Molecular mass by mass spectrometer. b) Amino acid sequence in the N-terminus end by EdmanDegradation c) Amino acid sequence and peptide profile by reduced peptide mapping d) Electrophoretic 'profile' and 'apparent' molecular' mass' by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) e) Hydrodynamic'volume by size-exclusion chromatography (SE-UPLC) technique using a fluorescence detector. f) Isoelectric point by capillary isoelectric focusing (cIEF) g) **Chromatographic'profile'and'polarity' BY** the reverse phase liquid chromatography (RP-HPLC) technique h) Upper order structure by fluorescence lifetime spectroscopy

	i) Secondary structure by circular dichroism j) Disulfide bond and peptide profile identification BY by non-reducing peptide mapping
Biological Activity	a) Binding to the receptor by flow cytometry b) Receptor binding by spectrophotometry in cells c) By G-CSF induced cell proliferation assay in cells 32D Clone 3 d) Biological Potency by in vitro cell proliferation using a mouse lymphoblastoid cell line (32D clone 3) e) Biological Potency by in vitro cell proliferation line NFS-60 (mice myeloblastic cells), f) In vivo assessment of the proliferative activity of Filgrastim using a neutropenic mouse model
Immunochemical properties	
Impurities	a. Aggregates by Identity and purity by molecular exclusion chromatography dad y SEUPLC-UV-FL b. Related isoforms by Reverse phase chromatography
Stability Studies	Stability studies are provided.
Non-clinical Comparison In-vivo Studies	(As already provided in Biological activity reproduced below:) a) Binding to the receptor by flow cytometry b) Receptor binding by spectrophotometry in cells c) By G-CSF induced cell proliferation assay in cells 32D Clone 3 d) Biological Potency by in vitro cell proliferation using a mouse lymphoblastoid cell line (32D clone 3) e) Biological Potency by in vitro cell proliferationline NFS-60 (mice myeloblastic cells), f) In vivo assessment of the proliferative activity of Filgrastim using a neutropenic mouse model
Clinical Comparison	i. Comparison of two presentations of filgrastim in Mexico used to mobilize hematopoietic totipotential cells from the bone marrow to the peripheral blood: prospective study in one single institution (19 Patient) ii. Only clinical reports are provided. Complete studies are not provided.

Decision of 291st meeting of RB:*Registration Board deferred the case for submission, of comparative Nonclinical studies under biosimilarity studies, by the firm.*

In response the firm has submitted comparative in-vitro non-clinical studies and in vivo assessment of the proliferative activity of Filgrastim using a neutropenic mouse model. While comparative toxicity studies are not provided for the which the firm has provided justification wherein it has been described that the product has been safely and effectively used in Mexico and in more than 8 countries since 2001. In 2014 the Mexican regulation was updated to converge with international guidelines, in this regard all biotechnological products were submitted to a regularization process according to the Official Mexican Standard NOM-257-SSA1-2014 "On matters of biotechnological medicines" and on the "Guide for establishing biocomparability of biotechnological drug product that contain Filgrastim as drug substance", to demonstrate its biocomparability against the reference drug product.And the said product i.e. Filatil (Filgrastim) was validated & renewed the marketing authorization in 2016 in the country of origin by submission the same data. And as per the guidelines of the country of the origin"**Toxicological studies will only be carried out if there is a need for information additional to that obtained in the *in vitro* studies. The duration must be justified and the pharmacokinetic behavior of the molecule and its clinical use must be taken into account**." Filatil has

presented biocomparability with the brand leader in the in vitro and in vivo biological activity assays, showing no signs that the assessment of the repeated dose toxicity was needed as part of the comparability exercise.

Decision: Registration Board deferred the case for submission of data of comparative non-clinical in-vivo repeat dose toxicity study by the firm.

19. Termination of Marketing Authorization of M/s Hospital Services & Sales, Karachi by its overseas Principal manufacturer Sichuan Yuanda Shuyang Pharmaceutical Co., Ltd, JieErNian, Zhonghe, Hi Tech Zone, Chengdu, China

The following product of M/sHospital Services & Sales, Karachi was approved in 258th meeting of Registration Board as per following details:

Manufacturer	**Brand Name & Composition**	**Document Details, Pack size & Shelf life**	**Decision of RB**
M/s Sichuan Yuanda Shuyang Pharmaceutical Co., Ltd, The 32nd Floor, First City Plaza, No. 308 of Shuncheng Street, Chengdu-610017, Sichuan, China, Manufacturing site: Sichuan YuandaShuyangPharmaceutical Co., Ltd, Hui Long, Zhonghe, Hi Tech Zone, Chengdu-610214, Sichuan, China	SUYA – IV 5g/VIAL (5%), 100mL Human Immunoglobulin (pH4) for Intravenous injection Each 100ml vial contains: Human Immunoglobulin ≥ 95%.....5g	CoPP No. 161100B0/57458 Valid till 04-09-2018	*Approved as per Import Policy for Finished Drugs. Firm will provide valid legalized CoPP and Chairman, RB will permit issuance of registration letter.*
	SUYA – IV 2.5g (5%), 50mL Human Immunoglobulin (pH4) for Intravenous injection Each 50ml vial contains: Human Immunoglobulin ≥ 95%.....2.5g	CoPP No. 161100B0/57457 Valid till 04-09-2018	
	SUYA – IV 1.25 /VIAL (5%), 25ML Human Immunoglobulin (pH4) for Intravenous injection Each 25ml vial contains: Human Immunoglobulin ≥ 95%.....1.25g	CoPP No. 161100B0/57455 Valid till 04-09-2018	

The inspection of manufacturing facility abroad was conducted by panel on dated12-13th July 2018in which panel "RECOMMENDED" the facility and rated VERY GOOD. The case has been processed for price fixation/ confirmation by the Costing & Pricing Division**.**

Now the , Legalized Letter of Cancellation (Termination letter) has been received by post on 7th April,2020 via Director PE&R division from Manager of International Trade Dept. Sichuan Yuanda Shuyang Pharmaceutical Co., Ltd China wherein it has been described that they have terminated the cooperation with Hospital Services & Sales, located at 13-C,Block 6, PECHS, Shahrah-e-Faisal, Karachi and decided to discontinue the cooperation with the said agent for the product Human Immunoglobulin for Intravenous Injection (1.25g,2.5g,5.0g,)(SUYA-IV).

Decision: Registration Board advised M/s Hospital Services & Sales, Karachi to submit updated Sole agency agreement within 02 months.

20. Change in address of importer applied by M/s Hipra Pakistan (Pvt) Limited, Lahore deferred in 295th meeting of Registration Board.

M/s Hipra Pakistan (Pvt) Limited, Lahore applied for the change in address of importer for their following veterinary vaccines as per following details:

Sr. No.	Reg. No.	Name of Product	Previous Address	Newly Applied Address
1.	094782	HIPRAGUMBORO-GM97	Office no.3&4,5th floor,105-B-II, Ali Tower, M.M Alam Road, Gulberg, Lahore.	3rd floor, Plot no.8, Block CCA, Phas w 6-C,DHA, Lahore.
2.	094781	HIPRAVIAR-SHS		
3.	094777	BRONIPRA-1		
4.	094769	HIPRAVIAR-B1/H120		
5.	094766	HIPRAGUMBORO-CH80		
6.	094779	HIPRAVIAR-CLON		
7.	094773	TOXIPRA-S7		
8.	094781	CORIPRAVAC		
9.	094770	AVISAN MULTI		
10.	099081	HIPRABOVIS SOMNI/Lkt		
11.	094783	HIPRAVIAR-ILT		
12.	094784	HIPRAGUMBORO-BPL2		
13.	094774	AVISAN SECURE		
14.	094768	HIPRAVIAR-TRT		
15.	094775	HIPRAVIAR-TRT4		
16.	094776	HIPRAVIAR-BPL2		
17.	094780	HIPRABOVIS-4		
18.	094771	HIPRAVIAR-S		
19.	094778	BRONIPRA-ND		
20.	094767	BRONIPRA-ND/IBD		
21.	096848	EVALON		
22.	094465	SELECTAN		
23.	094466	EFFICUR		
24.	094467	GENTAMOX		
25.	094468	HIPRALONA ENRO-S		
26.	094469	HIPRALONA ENRO-I		
27.	Under Process. Approved in 286th meeting.	HIPRAPOX		
28.	Under Process. Approved in 286th meeting.	NASYM		
29.	Under Process. Approved in 286th meeting.	HIPRADOG-7		

The firm has submitted the following documents:

a. Fee Challan of Rs. 5000/- for each product
b. Copy of initial registration letter
c. Copy of previous DSL.
d. Copy of new DSL indicating different proprietor.

All the products are recently transferred/fresh Registration (after 2018) in the name of the said importer therefore renewal is not yet.

It was noted that the proprietor of the company on the new DSL was also change and the NOC from the previous proprietor was not submitted instead the firm submitted notarized copy of the Resignation letter of the previous proprietor and notarized copy of the appointment letter of the new proprietor. And the firm

submitted that "The NOC is not possible to have from his side as he himself has resigned so that for your reference we have submitted his resignation letter"

The case was placed in 295th meeting of Registration board and the Board deferred the case for legal opinion by Legal Affairs Division of DRAP on not having NOC of from the previous proprietor. But before processing the case for legal opinion as per decision of the Board, the firm has submitted NOC from the previous proprietor i.e. Shadab Yunis Hakim.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s. Hipra Pakistan (Pvt.) Limited, Office no. 3 & 4, 5th floor, 105-B-II, Ali Tower, M.M Alam Road, Gulberg, Lahore to M/s. Hipra Pakistan (Pvt.) Limited, 3rd floor, Plot no.8, Block CCA, Phase w 6-C, DHA, Lahore for above products subject to storage facility verification report of new address.

21. Local human Biological applied for registration by M/s Hilton Pharma Karachi.

The following product for the local manufacturing biological drug was considered in 262nd Meeting of Registration Board held on 20-21stOctober, 2016and the Board decided as under;

Central Licensing Board has approved the manufacturing facility for rDNA products, As product is also of rDNA origin, which is evident from the provided certificate of analysis and other documents, thus Registration Bard approved Gluwell- Base 3ml Cartridge (Insulin Glargine 100IU). Insulin glargine will be imported in crystalline form from M/s Biocon India and will be formulated locally at M/s Hilton Pharma Karachi.

But later on the Registration Board in its 270th meeting advise the division of Biological drugs to come up with working paper in the next meeting. The final guidelines regulatory requirements of Biological drugs using rDNA technology has been approved in 278th meeting of Registration Board and it has been mentioned in the Guidelines that "***For the already registered drugs for local manufacturing the current guidelines shall apply".***

And the firm was advised to submit Biosmilarity data in light of decision of 278th meeting of Registration Board. Now the firm has submitted data which has been summarized below. The Detail of the product is as under;

Name of Manufacturer	M/s Hilton Pharma (Pvt.) Ltd. 13, sector 15, Korangi Industrial Area, Karachi.
Brand Name +Dosage Form + Strength	Gluwell-Base 3ml Cartridge Insulin glargine (100IU/ml)
Composition	Each ml cartridge contains: Insulin glargine ……100IU
Finished product specifications	BP Specification
Pharmacological Group	Therapeutic Protein
Shelf life	2 years when stored at 2-8 ^{O}C
Products already registered in Pakistan	Lantus by Sanofi
Type of Form Dy No & Date of application, Fee submitted	Form-5, Dy No & Date of initial Application. Dy No.2924/2016(R&I) dated 27-06-2016 Rs. 20,000 dated 27-06-2016
Demanded Price / Pack size	Price: As per DPC 3ml Cartridge Pack of 1's ,3's & 5's

The firm has submitted data as per the said guidelines. The submitted documents are evaluated as under;

Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	Documents submitted by firm
The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	The firm has submitted legalized copy of GMP but the manufacturing site mentioned is different from that was mentioned in the initial Registration dossier, provided copy of GMP at that time and Registration board meeting.
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	The firm has submitted legalized copy of Free Sale Certificate (FSC) but the product mentioned is for export purpose only (Not freely available as per provided FSC). Furthermore, the manufacturing site mentioned is different from that was mentioned in the initial Registration dossier, provided copy of GMP at that time and Registration board meeting.
The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Provided & Evaluated below
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	The firm informed that no Lot release certificate is required for such types of product in India. (The letter is from the importer side)
The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Provided
The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same),visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application.	Provided results for the following tests: Appearance, Identification, PH, Product related substances and impurities, Limit of High Molecular weight proteins, m-cresol Content, Assay (Insulin Glargin), Particulate Matters & Bacterial Endotoxin test. **Not Perform:** Osmolarity, sterility, Safety, toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques.
The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided as mentioned above except Sterility test, Total Zinc content, Glycol content
The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Provided
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	The firm has submitted Technology Transfer Agreement between Hilton Pharma & Biocon Limited dated 24th July 2009 but the specific wording as required in the Guidelines are not mentioned.
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the	The firm has provided SOP for Pharmacovigilance Surveillance.

manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	The firm has also provided Commitment on its letter head mentioning the said statement.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Commitment provided on the letter head
If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Commitment provided on the letter head
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Commitment provided on the letter head

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	a) Protein Content at UV 280 (by RP-HPLC method) b) Primary Structure: i. Intact Mass determination by Liquid Chromatography-mass spectrometry (LC-MS) ii. Molecular Mass (Reduced mass) determination by LC-MS iii. Peptide Mapping (Reduced) by LC-MS iv. Peptide sequencing by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) c) Secondary Structure & high order Structure i. Peptide mass fingerprinting under non –reducing conditions for confirmation of disulfide linkage by LC-MS ii. Disulfide linkage by 2D NMR iii. Secondary Structure by FT-IR spectroscopy iv. Circular Dichroism (Secondary Structure) by Far spectroscopy. v. Circular Dichroism (Tertiary Structure) by Near spectroscopy. vi. Determination of thermal stability by mean of Differential scanning calorimetry DSC vii. Determination of **Isoelectric point** (**pI**) by means of capillary isoelectric focusing (cIEF)
Biological Activity	Biological activity was carried out for insulin glargine injections by means of four different methods:. • Cell bases metabolic assay, • Mitogenic assay • Insulin receptor binding assay • IGF-1 receptor binding assay. Additionally in vivo bioassay /Insulin assay (USP 121 & USP 111) : Rabbit blood sugar method
Impurities	Determination of product related substances by mean of RS method
Stability Studies	Stability studies are provided.
Non-clinical Studies	A comparative 90 day toxicity study with recombinant Insulin Glargine (Biocon Ltd) and Lantus (Aventis Pharma) in Wistar Rats by subcutaneous route (Study no. G4668)
Clinical Studies	Open Label, Randomized, Multicentric Study to Establish Safety and Efficacy of Recombinant Insulin Glargine Manufactured by Biocon Ltd Compared to

	Lantus TM in Type 1 Diabetes Mellitus Patients. **(Total 226 evaluable patients)**

Remarks of Evaluator: As per Guidelines approved in 278th meeting of Registration Board, the following documents/data need to be submitted by the firm.

i. The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.
ii. The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.
iii. The firm has not performed Sterility test locally which is required as per above mentioned guidelines.
iv. The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.

Furthermore, the Safety/toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques is not been performed which is also not performed in quality comparison as per EMA assessment report of Biosimilar Insulin glargine.

Decision: Registration Board referred the case to Committee on Biological Drugs constituted in 273rd meeting of Registration Board for its recommendations on the requirements of toxicity studies and abnormal toxicity studies. Moreover, Registration Board nominated Lt. Gen. (R) Prof. Dr. Karamat Ahmed Karamat (HI-M, SI-M) as Chairman of said committee. However, following documents need to be submitted by the firm:

i. **Legalized GMP certificate of drug substance manufacturer abroad.**
ii. **Legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as evidence that the final product has been manufactured by same concentrate/ready to fill bulk.**
iii. **Data of sterility test performed locally on finished drug.**
iv. **An agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.**

22. Case of Termination of Marketing Authorization of M/s Medi Mark Pharmaceuticals Liaqat chowk, Sahiwal by its overseas Principal manufacturer Changzhou Qianhong Bio pharma Co., Ltd. No.128 Xueye Road, Xinbei District, Changzhou, Jiangsu, China

The following product of M/s Medi Mark Pharmaceuticals Liaqat chowk, Sahiwal approved in 278th meeting of Registration Board as per following details:

Manufacturer	**Brand Name & Composition**	**Decision of RB**
M/s Changzhou QianhongBio-pharma Co., Ltd. Address 1: No.192 Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China. Address 2: No.128 Xueye Road, Xinbei District, Changzhou, Jiangsu, China	**Mediren Inj**. 25000IU/5ml Each 5ml Vial contains: Heparin Sodium…… 25000IU/5ml USP Specs	Keeping in view the availability of product in country of origin as per submitted CoPP and Heparin injection being non-rDNA pharmacopoeial product, Registration Board approved the Mediren Inj. 25000IU/5ml as per valid legalized CoPP subject to price fixation by Federal Government and compliance of current Import Policy for Finished drugs.

The inspection of manufacturing facility abroad has been conducted by panel of inspectors (Mr. Muhammad Abdul Ghaffar , Deputy Director (Health & OTC), DRAP Islamabad & Prof. Dr. Abdul Haleem Khan, Member

Medical Devices Board on dated 29th-30th September 2019 in which panel "RECOMMENDED" the facility and rating **VERY GOOD.**

After receiving the above inspection report , Legalized Letter of Declaration (Termination letter) has been received by post on 28th October,2019 from Assistant of API Business Unit Changzhou Qianhong BiopharmaCo., Ltd. China wherein it has been described that Changzhou Qianhong Bio-pharma Co., Ltd.No.128 Xueye Road, Xinbei District, Changzhou, Jiangsu, China have decided to terminate the partnership, and cancel the agreement and power of attorney in the region of Pakistan with Medi Mark Pharmaceuticals (Pvt) Ltd. Addressed: Liaquat Chowk, Sahiwal, Pakistan for the product Heparin Sodium Injection 25000IU/5ml due to the fact that Medi Mark Pharmaceutical (Pvt) Ltd has failed to finish the registration and start the marketing of the said product within the validity period of agreement. And they also submit copy of email address to CEO DRAP, Chairman Registration Board Director Biological Drugs and Secretary Registration Board enclosing the same comments.

Decision of 293rd meeting of RB: Registration Board deliberated that the above said court order does not bar for further processing of the case. Hence, Registration Board decided to issue show cause notice to M/s Medi Mark Pharmaceuticals, Sahiwal regarding the cancellation of their authorization for registration of Mediren Injection by M/s Changzhou Qianhong Bio-pharma Co., Ltd., China.

As per above decision of the Board, show cause letter was issued to the firm and in response the firm has requested to give some more time to reply the show cause notice in proper way**.**

Decision: Registration Board advised M/s Medi Mark Pharmaceuticals, Sahiwal to submit updated Sole agency agreement within 02 months.

23. Case of Termination of Marketing Authorization of M/s Marush Pvt Ltd Lahore by its overseas Principal manufacturer M/s Shchelkovo Biocombinat, a Federal State Enterprise Russian Federation.

The following product of M/s Marush (Pvt.) Ltd., Lahore approved in258th meeting of Registration Board as per following details:

Manufacturer	**Brand Name & Composition**	**Decision of RB**
M/s Shchelkovo Biocombinat, Biocombinat township, Shchelkovskii, District Moscow region, Russian Federation. Jiangsu, Russia.	Cultural monovalent and polyvalent adsorbed Inactivated vaccine against Foot and Mouth disease. Each dose contains: Inactivated FMD virus antigen of strains: A (Turk06)…6PD50 O (Pan Asia2)……6PD50 Asia 1 (Sind08)…….6PD50 **Shelf Life:** 18 months (20C-80C)	Approved as per import policy and as per valid legalized CoPP

The product is waiting of constitution of panel for inspection facility abroad and now email has been received to Director Biological via Chairman Registration Board fromUlyashkin Alexey Head of commercial department Shchelkovo Biocombinat, Russia (sales@biocombinat.ru) wherein it has been mentioned that Schelkovo Biocombinat a Federal State Enterprise of the Russian Government, in the year 2018 has terminated the Distribution Agreement for Pakistan's market with Marush and request to not consider any dealing of Marush (Pvt) Ltd on behalf of Schelkovo Biocombinat. The Notice of Termination of Agreement in the name of M/s Marush Pvt Ltd dated 1-04-2018 is also attached with said email.

Decision: Registration Board decided to issue show cause notice to M/s Marush Pvt. Ltd., Lahore under section 42 of the Drugs Act, 1976 read with rule 24 (17) of the Drugs (Licensing, Registering, Advertising) Rules, 1976 regarding the cancellation of their authorization for registration of Cultural monovalent and polyvalent adsorbed Inactivated vaccine against Foot and Mouth disease by M/s Shchelkovo Biocombinat, Biocombinat township, Shchelkovskii, District Moscow region, Russian Federation. Jiangsu, Russia.

24. Delisting of BCG vaccine BP of M/s M & M Pharma, Lahore from WHO prequalification list

The following product of M/s M & M Pharma, Lahore was approved in 268th meeting of Registration board as per following details.

Manufacturer	Brand name & composition	Document details
Greensignal Bio Pharma Limited,No. 49, Pappankuppam village, Gummidipoondi taluk Tiruvallur District Chennai-601201, India	**BCG vaccine BP** Each freeze dried vaccine vial contains: Mycobacterium bovis BCG, Danish strain 1331, Live attenuated equivalent to 20 doses…….1mg Sodium glutamate.....1.5%w/v Shelf Life: 24 months	Legalized CoPP No. L.DIS No. 17307D1/4/2016 dated 30-09-2016 Free Sale certificate No.L.Dis. No. 14450/ D1/4/2015 dated 19-09-2015 Sole agent/ Authority letter dated 19-11-2016

The product is imported from India and its WHO prequalification is been removed on *1 November 2019* as per online WHO websites vide below mentioned link **but the firm i.e. M/s M & M Pharma, Lahore did not intimate DRAP till date.**
https://www.who.int/immunization_standards/vaccine_quality/TB_Vaccine-withdrawal/en/

And the statement on WHO website is reproduced as under;

"1 November 2019 - WHO today removed a freeze-dried BCG vaccine for the prevention of tuberculosis from its list of prequalified vaccines for procurement by UN agencies. The decision follows a number of evaluation activities carried out by WHO to monitor the performance of both the vaccine and its manufacturer, GreenSignal Bio Pharma Pvt Ltd., India.

Alternative sources of prequalified BCG vaccines are available.

The Freeze-Dried BCG vaccine in question was prequalified by WHO in November 2015. As part of its efforts to ensure continued supply of quality-assured vaccines, WHO has recently carried out post prequalification monitoring activities – namely, target independent testing, submission and assessment of Prequalified Vaccine Annual Reports and inspections of the manufacturing site.
The outcome of the WHO inspections of the manufacturing site, and the company's response to the findings of those inspections were not satisfactory. The last two WHO inspections concluded that the company was operating at unacceptable levels of compliance with WHO guidelines on good manufacturing practices, potentially endangering the performance of the vaccine and posing a high risk to recipients.
WHO will proceed to the immediate removal of the vaccine from the WHO list of prequalified health products and recommends continued vaccination with prequalified BCG vaccines from alternative sources.
WHO has advised Green Signal Bio Pharma Pvt Ltd., India to take appropriate action, including immediate recall of remaining vials of the lots of the freeze-dried BCG vaccine manufactured and distributed in 2019."

Decision: Registration Board deliberated that the product was registered and exempted from inspection of manufacturer abroad on the basis of then WHO Prequalification. Now, WHO has removed the vaccine from WHO list of prequalified products, therefore, Registration Board decided to issue show cause notice to M/s M&M Pharma, Lahore under section 42 of the Drugs Act, 1976 read with rule 24 (17) of the Drugs (Licensing, Registering, Advertising) Rules, 1976 regarding the delisting of their product BCG Vaccine BP (Reg. No. 084608) from the list of WHO Pre-qualified vaccines.

25. Imported Veterinary Biological applied by M/s Huzaifa International, Sargodha deferred in 290th meeting of Registration Board.

The following veterinary vaccine was deferred in 290th meeting of Registration board;

Name of Importer	M/s Huzaifa International, Address: Commercial Area, AzizBhatti Town, Sargodha, Pakistan
DSL details	Copy of DSL Address: M/s Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity : 20th November-2019 Status: License to sell drugs as Distributor
Name of Manufacturer	M/s Komipharm International Co., Ltd. Address:17, Gyeongje-Ro, Siheung-Si, Gyeonggi-Do, South Korea [Before Address System CHange: 1236-6, Chongwang-Dong, Shihung-Si, Kyonggi-Do, South Korea]
Brand Name +Dosage Form + Strength	Pro-VacChek ND (Lyophilized Newcastle Disease Virus Live Vaccine)
Composition	Active Ingredient (s) and Amount (s) per unit dose: Newcastle Disease Virus (Ulster 2C strain) $\geq 10^{5.0}EID_{50}$ **Excipient:** LPGG ……40% **Composition of LPGG:** Lactose……74.62g Monopotasium phosphate ……..0.53g Dipotasium phosphate……1.25g Monopotasium L-glutamate……0.83g Gelatin……10g Distilled water……1000mL
Finished product specifications	Ph. Eu specifications
Pharmacological Group	Poultry Vaccine
Shelf life	24 months (When stored at 2-8 C° at the Dark place)
International availability	Not Provided.
Products already registered in Pakistan	The strain Ulster 2C is available by Lachman which is inactivated virus vaccine as per our record while applied vaccine is Live virus vaccine.
Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 27460(R&I) Dated 9th August 2018 Rs. 100,000/- 2nd August, 2018
Demanded Price / Pack size	Decontrolled/ 1000 doses
General documentation	***Original Legalized Free Sale Certificate (FSC):*** **Issued by:** Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rular Affairs of the Republic of Korea • **Issued on:** 12-01-2018 ***Original Legalized GMP Certificate:*** • **Issued by:** As mentioned above **Issued on:**19-06-2018.
Remarks of Evaluator	This is to inform the Board that the strain Ulster 2C is available by Lachman which is inactivated virus vaccine as per our record while applied vaccine is Live virus vaccine.

Decision of 290th meeting of RB: Registration Board deferred the case and advised DBER to compile the data of all Newcastle disease virus vaccines (live and killed) in coordination with Dr. Qurban Ali, Member Registration Board.

The list of Newcastle disease virus vaccines (live and killed) registered since 2014 by the Division of Biological Drugs was compiled from the excel sheet maintained at Division level and Newcastle disease virus vaccines (live and killed) registered before 2014 was compiled from the data in excel sheet provided by PE&R division. The comprehensive list of all Newcastle disease virus vaccines (live and killed) have been prepared which is annexed and processed on file to be shared with Dr. Qurban Ali, Member Registration Board for his comments/recommendation.

Decision: Registration Board deferred the case for confirmation of already registered Newcastle disease formulation and same will be shared with Dr. Qurban Ali Member Registration Board for review.

AGENDA ITEM NO.1 – OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.		
S. No.	**Subject**	**Status**
01.	MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD DRUG BICOLAX TABLET B.NO.4E009	
02.	CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.	03 personal hearings
AGENDA ITEM NO. 02: NEW / ONGOING QC CASES		
S No.	**Subject**	**Status**
01	MANUFACTURE & SALE OF SUB-STANDARD ZANCPAL SUSPENSION, BATCH NO. D281 BY M/S ZANCTOK PHARMACEUTICAL LABS, HYDERABAD.	Personal hearing
02	MANUFACTURE & SALE OF SUB-STANDARD KEYGESIC 75 TABLETS, BATCH NO. 2918 BY M/S BENSON PHARMACEUTICALS, ISLAMABAD.	**-do-**
03	OREDRED NOT TO DISPOSE OF UNDER SECTION 18 (1) (I) OF THE DRUGS ACT, 1976, EXTENSION IN PERIOD.	**-do-**
04	MANUFACTURE & SALE OF ADULTERATED & SUBSTANDARD ADYNEPH INJECTION, REG. NO. 085777, MFG. DATE MAY, 2018, EXP. DATE APRIL 2020, BATCH NO. AD-10418, MANUFACTURED BY M/S BAJWA PHARMACEUTICALS (PVT.) LTD., LAHORE.	**-do-**
05	MANUFACTURE & SALE OF ADULTRATED & SUB-STANDARD RHINEX P SYRUP, BATCH. NO. 051 M/S OPAL LABS; (PVT), LTD. KARACHI.	**-do-**
06	MANUFACTURE & SALE OF SUB-STANDARD ZAYPEP SUSPENSION, BATCH NO.18023 BY M/S ZAYNOON PHARMACEUTICALS (PVT) LTD, PESHAWAR.	**-do-**
07	MANUFACTURE & SALE OF SUB-STANDARD ALFASUN 1MCG CAPSULES BATCH NO.C325 BY M/S HISUN PHARMACEUTICAL INDUSTRIES, GADOON.	**-do-**
08	MANUFACTURE & SALE OF SUB-STANDARD DRUG PEARLE WHITE COTTON BANDAGE B.P TYPE-II, BATCH NO.PWB-0901, REG. NO. 042254 MANUFACTURED BY M/S SULTAN COTTON & BANDAGE, MIRPURKHAS, SINDH.	**-do-**
09	MANUFACTURE & SALE OF SUB-STANDARD DRUG NIM D3 INJECTION BATCH NO.P560 REG. NO. 090190 MANUFACTURED BY M/S NIMRALL LABORATORIES, ISLAMABAD.	**-do-**
10	CASE REFERRED BY PQCB, PUNJAB REGARDING APOCLOX 500MG INJECTION MANUFACTURED BY M/S PDH LABORATORIES.	**-do-**
11	CASE REFERRED BY PQCB, PUNJAB REGARDING METHOD OF DOSAVIL INJECTION, BATCH NO. AM-182, MANUFACTURED BY M/S DOSACO LABORATORIES.	**-do-**
12	CASE REFERRED BY PQCB, PUNJAB REGARDING PROVISION OF NUGATORY METHODOF INJ. COLIMOXIN TO DTL, BAHAWALPUR BY M/s SELMORE PHARMACEUTICALS.	**-do-**
13	CASE REFERRED BY PQCB, PUNJAB REGARDING NON-PROVISION OF METHOD OF ANALYSIS AND STANDARD BY	**-do-**

	MS LAWARI PHARMACEUTICALS FOR POLWARI 100MG TABLET.	
14	MANUFACTURE & SALE OF SUB-STANDARD COTTON BANDAGES B.P TYPE-II, BATCH NO. CBB-17L047 BY M/S THE NATIONAL ABSORBENT COTTON MILLS CO., KARACHI.	**-do-**
15	MANUFACTURE AND SALE OF SPURIOUS DRUG (QUINOZEF 250MG TABLETS, BATCH NO. AP0014) – M/S AMBRO PHARMA (PVT.) LTD., ISLAMABAD.	**-do-**
16	CASE REFERRED BY PQCB, PUNJAB REGARDING NON-PROVISION OF METHOD OF ANALYSIS BY M/S CREST PHARMACEUTICALS (PVT.) LTD.	**-do-**
17	CASE REFERRED BY PQCB, PUNJAB REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE METHOD OF ANALYSIS.	**-do-**
18	INVESTIGATION OF SUB-STANDARD MEGAFEN 90ML SUSPENSION (IBUPROFEN 100MG/5ML) BATCH NO. 1-526 M/S ALBRO PHARMACEUTICALS (PVT.) LTD., LAHORE INSPECTION THEREOF.	
19	CASE REFERRED BY PQCB, PUNJAB REGARDING CAPSULE CAPSOL ZOL 40, BATCH NO. 0198, MANUFACTURED BY M/S FESTAL LABORATORIES, JINNAH INDUSTRIAL ESTATE, LINK KATTARBAND RAOD, LAHORE.	
20	CASE REFERRED BY PQCB, PUNJAB REGARDING SUBSTANDARD MEDIDOL TABLET, MANUFACTURED BY M/S MIDICON PHARMA (PVT.) LTD., PESHAWAR.	
21	CASE REFERRED BY PQCB, PUNJAB REGARDING KAYMAX 75MG SUGAR COATED TABLETS, B# GX1733, MANUFACTURED BY M/S QUAPER (PVT.) LT., 26-A S.I.E LAHORE ROAD, SARGODHA.	
22	CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION SULFAPRIME, BATCH NO. I-109, MANUFACTURED BY M/S ATTABAK PHARMA ISLAMANBAD.	
23	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 346, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.	
24	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 348, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.	
25	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOPRIN TABLETS 75MG, B# 006502L, MANUFACTURED BY M/S PACIFIC PHARMACEUTICALS (PVT.) LTD., 30TH km MULTAN ROAD, LAHORE.	
26	MANUFACTURE & SALE OF SUB-STANDARD DRUG REVOX 500MG TABLETS BATCH NO. 17GT01 REG. NO. 045265 MANUFACTURED BY M/S UNI-TEICH PHARMACEUTICAL (PVT.) LTD. KARACHI.	
27		

AGENDA ITEM NO. 01– OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.

It is submitted that the FID, Q @K vide letter vide letter 3-1/2009-FID(Q)K dated 28.01.2019 stated that the Honorable Drug Court, Quetta has passed the orders during proceedings on 3rd December, 2018 in the case titled "Surat Khan Medical Store and others" to provide the list of pending cases of DRAP, Quetta. Moreover, the FID Quetta requested vide letter No.3-1/2019-FID(Q) K dated 05th August 2019 "the old pending cases may kindly be discussed in the Boards concerned on priority basis and necessary decisions may kindly be passed in order to submit the status/copies of decisions in the Honorable Drug Court, Quetta".

As per information provided regarding the cases referred by the Honorable Drug Courts, Quetta and FID, Quetta @ Karachi, as per records shared by DRAP Office Quetta, following are the details of cases. The FID Quetta claimed that the cases were submitted to the Chairman CLB&RB, Government of Pakistan, de-funct Ministry of Health, Islamabad in the said years. As per available record of the section it seems that the referred cases by the FID Quetta were not processed and found pending to date due to reasons not revealed yet.

In light of request of FID Quetta, the agenda of said pending cases have been prepared according to records available in the section and the records shared by DRAP Office Quetta, for the consideration of Board please. The details of the cases are as under:-

CASE NO.01:- MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD DRUG BICOLAX TABLET B.NO.4E009

That the then FID Quetta Mr. Syed Abdul Saleem vide letter no.F.12-26/DCA-QTA/1708 dated 08th September, 2008informed that the instant case was sent by the then FID Mr. Adnan Faisal Saim vide his letter No.12-26/DCA-QTA/Bicolax-3752 dated 28thOctober 2005.

02. As per case forwarded by the then FID Quetta Mr. Adnan Faisal Saim that he visited the premises of T.K Traders Dr. Bano Road Quetta on 21st May 2005 from where a sample of drug namely BicolaxB.No.4E009 labeled to be manufactured by M/s Epoch Pharmaceuticals Pvt Ltd Karachi (along with other samples of drugs) was taken from the purpose of test/analysis under section 19(2) of Drugs Act 1976 on Form-3.

03. That the then FID Quetta informed that the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide his office letter No.F.5/DCA-QTA/Sample-3020 dated 25th May 2005 on form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB & RB Islamabad vide his letter No.F.5/DCA-QTA/Sample-3028 dated 25th May,2005. A portion as manufacturer portion of said drug was also send to M/s Epoch Pharmaceutical Pvt. Ltd Karachi vide his office letter No.F.5/DCA-QTA/Sample-3022 dated 25th May, 2005.

04. That the then FID Quetta informed that M/s T.K traders Quetta was asked to provide invoice with warrantee in respect of drug in question vide office letter No.F.5/DCA-QTA/Sample-3047 dated 28thMay 2005 and on non-responding reminders vide letter No.F.5/DCA-QTA/Sample-3143, 3179, 3297 dated 21.06.2005, 11.07.2005 and 29.07.2005 respectively & show cause notice vide letter No.F.5/DCA-QTA/Sample-3390 & 3427 dated 20.08.2005 & 24.08.2005 respectively. M/s T.K Traders Quetta submitted vide letter No. TK/16-8/05 dated 23.08.2005, copy of their letter addressed to M/s Epoch Pharmaceutical Pvt Ltd Karachi for provision of invoice for said drug. Thereafter a letter vide No.F.5/DCA-QTA/Sample-3426 dated 24th August 2005 was dispatched to M/s Epoch Pharmaceutical Pvt. Ltd Karachi for explanation but firm submitted copy of their invoice with warrantee bearing No.1091 dated 28.03.2005 for said drug vide letter No. Nil dated 30.08.2005. M/s T. K Traders Quetta has also submitted invoice with warrantee bearing No.1091 dated 28.03.2005 of M/s Epoch Pharmaceuticals Pvt. Ltd Karachi vide their letter No. T. K/17-08/2005dated 05.08.2005 received on 05th September 2005.So the warrantor portion of said sample of drug was sent to M/s Epoch Pharmaceuticals Pvt. Ltd Karachi vide his office letter No.F.5/DCA-QTA/Samples-3518 dated 13th September 2005.

05. That the then FID Quetta also informed that the Director, CDL, Karachi vide his test report no.R.1286/2005 dated 26th August 2005 dated 26th August 2005 declared the sample of **Bicolax Tablet Tablet B.No.4E009** as **Misbranded & Substandard.**

06. That the then FID Quetta also reported that a show cause notice was issued to M/s Epoch Pharmaceuticals Pvt. Ltd Karachi for manufacturing a substandard drug, issuing false warranty, stocking for sale and selling substandard drug namely Bicolax Tablet B.4E009 and also asked for provision of following documents vide office letter No.F.12-26/DCA-QTA/Bicolax-3530 dated 21st September 2005.

a). Production/analysis and sale record with copies of invoice of paracetamol tablet b.no.10.
b). Copy of Registration certificate of Bicolax Tablets.
c). Recall all the stocks of Bicolax Tablet B.No.4E009 from the market under intimation to this office.
d). Name addresses and attested copies of CNIC of the following personal of firm
   i. Management Director/Chief Executive/owner/partner
   ii. Director/Directors.
   iii. Plant Manager
   iv. Approved production Incharge.
   v. Approved QC Incharge.
   vi. Warehouse Incharge.

07. That the then FID Quetta also informed that M/s Epoch Pharmaceuticals Pvt Ltd instead of submitting their reply along with information asked for, challenged the test report and requested for test/analysis of said product from NIH Islamabad vide letter No. Nil dated 11th October 2005.

08. That the then FID Quetta also stated that M/s T.K Traders Quetta was asked for provision of stock position of referred batch of Bicolax Tablet and that stop further sale vide office letter No. F.12-26/DCA-QTA/Bicolax-3532 dated 21st September 2005. M.K Traders Quetta submitted Nil report vide letter No. T.K 18-10/05 dated 26.10.2005

09. That keeping in view the detail investigation the then FID Quetta proposed that a panel (in which the FID Quetta also nominated as member) may kindly be constituted for details inspection for checking the production test/analysis and sale record of firm

10. That keeping in view the above stated facts the then FID Quetta also stated that it seems that the firm M/s Epoch Pharmaceuticals has violated the sections 23(1)(a)(iii), 23(1)(v),23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i).

11. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of BICOLAX TABLET B.NO.4E009 with manufacturing date 12/04:

i. Production Incharge – Qamar ul Huda
ii. Quality Control Manager – Mrs Seema Ashaqeen
iii. Managing Director – Salim Ismail Patel

12. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID (Q) K dated 05th August 2019, the case was placed before the Registration Board. The Board after detailed deliberation decided to issue the show cause notice for violating the sections 23(1)(a)(iii), 23(1)(v), 23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i) against following responsible person(s) of the firm i.e. M/s Epoch Pharmaceuticals:
   i. M/s Epoch Pharmaceuticals through it CEO/MD
   ii. Managing Director – Salim Ismail Patel
   iii. Production Incharge – Qamar ul Huda
   iv. Quality Control Manager – Mrs Seema Ashaqeen

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:

a. Prosecution in the Court of competent jurisdiction.
b. Cancellation/suspension of registration.
c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

13. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

*That Federal Inspector of Drugs, Quetta during inspection of M/**s T.K Traders, Asad Building, Dr. Bano Raod, Quetta** on dated 21.05.2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976**:-***

Name of Product:	*Bicolax Tablet*
Batch No.	*4E009*
Manufacturing Date:	*12-04*
Expiry Date:	*12-07*
Manufacturer:	*M/s Epoch Pharmaceutical, Karachi*

*2. The Federal Government Analyst, vide test/analysis report No.1286/2005 dated 26th August, 2005 had declared the sample as of "**Misbranded &Sub-Standard**" quality **(Copy Annexed)**.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

[…] to issue the show cause notice for violating the sections 23(1)(a)(iii), 23(1)(v), 23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i) against following responsible person(s) of the firm i.e. M/s Epoch Pharmaceuticals:

1. *M/s Epoch Pharmaceuticals through it CEO/MD*
2. *Managing Director – Salim Ismail Patel*
3. *Production Incharge – Qamar ul Huda*
4. *Quality Control Manager – Mrs Seema Ashaqeen**. […]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. *Prosecution in the Court of competent jurisdiction.*
ii. *Cancellation/suspension of registration.*
iii. *Any other action the Board may deem fit under the law.*

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.

Proceedings and Decision of 292nd Meeting of Registration Board held on 01st-02nd October, 2019

14. That None appeared on behalf of the accused before the Board (neither in person nor by any attorney/pleader) nor submitted any written reply to the show cause notice till 01st October, 2019.

Decision of 292nd meeting of Registration Board.

15. The Board decided to grant last opportunity of personal hearing to the accused persons before the Registration Board in its upcoming meeting with direction that no further adjournments will be granted.

16. The decision of the Board was communicated to the accused persons vide letter no. 03-46/2019-QC (292-DRB) dated 12.11.2019.

17. The firm M/s Epoch Pharmaceuticals, Plot No. 83-85, Sector No. 15, Korangi Industrial Area; Karachi- Pakistan vide their letter no. NIL dated 20.11.2019 submitted reply which is reproduced as under:

"With reference to your letter No. F.03-46 /2019-QC (292-DRB) dated 12th November 2019, received by us on 19th November 2019, that the board decided to grant last opportunity of Personal Hearing to the accused person before Registration Board Meeting in its upcoming meeting with the direction that no further adjournment will be granted.

This is to inform you that a letter No. F.21-26/DCA-QTA/Bicolax 3530 dated 21/09/2005 received by us on 5th October 2005. Our Technical Director had appeared in honorable board on 11th October 2005 and disused the matter and submit the reply. After that Honorable board decided to cancel the registration of Bicolax 5 mg Tablets Registration # 012833, copy enclosed.

Similarly, this case was again received by letter No. F.03-41/2019-00(291 DRB) dated 19lh September 2019 received on 27th September 2019 Ministry of health provided us the opportunity of Personnel hearing which we availed and our representative appear on 30th September 2019 and discuss the matter and submit the reply which is self-explanatory, copy enclosed.

Honorable Board had already decided to cancel the registration of Bicolax Tablet 5mg (Reg. No. 012833) and letter no. F-1-51/2005Reg-II (pt) dated 30th June, 2006 and we have accepted the decision of the Honorbale Board in comply with the direction of Central Licensing Baord and stop manufacturing of Bicolax Tablet 5mg since June 2006 (copy enclosed).

Now again on 19th November 2019 we received a letter in which board decided to grant last opportunity of Personnel Hearing.

We are requesting you to pl. suggest that this opportunity is still needed that product has already been deregistered since last 13 years.

We are enclosing all the required correspondence for your ready reference.

Again requesting to consider this reply for Bicolax 5 mg Tablets Reg # 012833 and close this matter."

Proceedings and decision of 293rd Meeting of Registration Board:

18. The Board was apprised that the show cause notice and personal hearing letters were issued to the accused persons in the light of decision of the Board, the firm has submitted written reply reproduced in para 17 above, however no one appeared before the Board either in-person or by authorized legal counsel.

19. The Board after detailed discussion, deliberations, considering the facts and written reply of the firm decided as under:

i. **As the registration of the product has already been cancelled by the Registration Board vide letter dated 30th June, 2006, the Board constituted the following panel to conduct a thorough cGMP inspection of Tablet Section of the firm:**
    a. **Rafiq Alam**
    b. **Area FID, Karachi**
    c. **Affan Ali**

Directed the FID, Quetta to hand over the case to Provincial Quality Control Board, Baluchistan to the extent of M/s T.K Traders Quetta for violating the provisions of section 23(1)(a)(x), 23(1)(i) of the Drugs Act, 1976.

The above said decisions of the Registration Board were communicated to the constituted panel and FID, Quetta vide No.F.03-65/2019-QC (293-RB) dated 22-04-2020 with request to comply with the decision of the Registration Board and report of inspection be provided **within 15 days** positively for consideration of Board, please.

In response to the Decision of the 293rd meeting of RB, M/s Epoch Pharmaceuticals vide reference No.Nil dated 11-05-2020 submitted their reply and is reproduced as under;

- *A letter No.F.12-26/DCA-QTA/Bicolax 3530 dated 21-09-2005 on the subject cited above. Our Technical Director and Managing Partner had appeared in honourable Board on 18-03-2206 and discussed the matter and submit the reply. After that the Honorable Board decided to cancel the Registration of Bicolax 5mg Tablets reg.# 012833.*
- *After Honorable Baord decision to cancel the Registration of Bicolax tablets 5mg Reg. No. 012833 in letter No.F.1-51/2005 Reg-II (pt) dated 30-06-2006and we have accepted the decision of the Board and comply with the directions of Central Licensing Board and stop manufacturing of Bicolax tablets 5mg since 2006.*
- *Through inspection had been conducted by the panel on 20-10-2010.*

- *Similarly the case was again received by letter No.F.03-41/2019-QC (291 DRB) dated 19-09-2019. Ministry of Health provided us the opportunity of personal hearing which was availed by us and our representative appear on 30-09-2019 and submit the reply.*
- *Product already been deregistered since around last 13 years so we presumed that the case is now closed by licensing Board therefore as per standard procedure we have disposed of the batch document record and the keeping samples all the licensing staff has now been changed who can brief the process.*
- *Respected sir our humble request to withdraw the letter of panel inspection.*

FID-II, DRAP, Karachi vide reference No.F.000425/2020-FID-II (K) dated 31st August, 2020 has forwarded the panel GMP inspection report of M/s Epoch Pharmaceuticals conducted by the panel constituted in 293rd meeting of the Registration Board. Inspection report is reproduced as under;

i. ***Inspection Site:***

M/s Epoch Pharmaceuticals (Pvt.) Ltd. is situated at Plot # 83-85, Sector 15, Korangi Industrial Area, Korangi, Karachi, Pakistan.

ii. ***Inspection Date:***

The inspection was carried out on Monday, 17th August 2020.

iii. ***Inspectors:***

The following inspectors of Drug Regulatory Authority of Pakistan were authorized to inspect/audit the firm:

1. *Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi*
2. *Mr. Abdul Rasool Shaikh, Area Federal Inspector of Drugs-II, DRAP, Karachi.*
3. *Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi*

iv. ***Reference:***

The firm has been granted Drug Manufacturing License (by way of formulation) number 000425, valid till 2021.

The inspection was carried out on the instruction of Drug Registration Board, DRAP for detail cGMP inspection of Tablet section vide letter No.F.03-65/2019-QC (293-RB), dated 22nd April, 2020.

v. ***Introduction:***

M/s Epoch Pharmaceuticals (Pvt.) Ltd., is a national pharmaceutical manufacturing company based at Karachi started its operations in 1998 with Manufacturing License Number 00425. The firm is engaged in manufacturing of solid oral dosage forms (i.e. tablets, capsules, powder for oral suspension), liquid syrup, cream/ointment, dedicated sections of cephalosporin, separate sections for oral penicillin, separate sections for veterinary products and sterile liquid injection and sterile ophthalmic drops.

vi. ***Scope of Inspection:***

As per TORs of the reference DRAP Islamabad letter a detailed inspection of their tablet section, stores, QC Lab was carried out and respective documentations were also reviewed in detail.

vii. ***Personnel met/accompaniedduring the inspection:***

1. *Mr. Saleem Abu Bakar, Managing Director*
2. *Mr. Salman Saleem, Chief Operations*
3. *Mr. Sohail Qasim Khan, Manager Quality Assurance*
4. *Ms. Zeenat Azhar, Head of Quality Control*
5. *Ms. Farhat Baigum, Head of Production*

viii. ***Inspectors Team's findings and observations relevant to the inspection; and deficiencies***

Pharmaceutical Quality System

During targeted inspection the panel found compromised quality management system starting from procurement of production materials from un-approved sources, inappropriate and un-controlled storage conditions, sub-optimal production conditions and more than that lack of necessary quality

documents, overall resulting in un-safer products. However certain instant working SOPs and controlling documents were shown during inspection, which were found deficient of key quality elements.

Personnel

The firm has hired key personnel without well-defined written authority, training and necessary relevant experience.

Premises & Equipment:

The tablet section was seen built as per provided design, which has to be regularized and approved. The flow of men &material and poor sanitation level might amplify the chances of cross-contamination among the productionas there were no proper buffers/air-locks and proper written plan to minimize the risks of cross-contamination was not available. The processes were found un-validated and almost all equipment were seen without proper written qualification documents. Certain key production machines like FB Dryers and bag filters used in drying were found key sources of cross-contamination, as cleaning procedures were not validated.

Certain walls of tablet sections were peeling off and floor was cracked resulting in bad maintenance and accumulation of dust and pathogens in claimed controlled areas. The panel was not shown any preventive or emergency maintenance plan available with the management of the firm.

Warehouses were not maintained properly, materials were seen exposed to un-controlled and un-wanted environmental conditions. The storage areas were provided with low lighting, the merely ducts provided there were open and no false ceiling was provided.

Documentation:

During inspection the firm was advised to provide key quality documents like site master file, validation and calibration plan, HVAC design with qualification documents, certain key working SOPs, preventive maintenance plan, stability studies program, self-audit documents, training program, change control management, controlling the deviations, OOS and OOT etc. Among those only a few incomplete and insufficient documents were provided. The panel found a very poor documentation control, which may badly affect the quality and safety of product the firm manufactures.

Production:

The tablet section has been provided with un-qualified HVAC System which was found incapable of reducing the chances of contamination and cross-contamination and can provide better safety to working personnel. Most of the bags of active materials were seen without necessary initial sampling and testing as required under GMP guidelines, instead seen tagged with released labels. In-appropriate sampling plan and procedures were seen in place. In-appropriate and irregular quality checks were noted in one of the BMR wherein apparent OOS were neglected and product was released for marketing. Overall a feeble production system noted in place.

Quality Control:

The firm has quality control laboratory for testing of bulk as well as finished goods with requisite equipment. The stability program of the firm needs to be improved with proper implementation.

ix. ***Conclusion & Recommendation:***

Keeping in view the above-mentioned facts and observations, the panel found the firm operating at sub-optimal GMP conditions particularly in tablet section and might not be allowed to carryout it's manufacturing under those conditions. All the major observations pointed out during the inspection were discussed in detail with the management of the firm and they showed interest to halt voluntarily their manufacturing operations and in addition to that the firm has submitted in written improvement plan to the panel for further consideration of the Board.

Proceeding and Decision of 296th meeting of Registration Board.

Registration Board after detailed deliberations, considering the inspection report forwarded by the panel constituted by the Board in its 293rd meeting decided as follows;

- **QA&LT Division shall process the panel report by its own, as per their prescribed procedure without waiting for the minutes of the 296th meeting of Registration Board.**
- **Registration Board also recommended the suspension of the tablet section to the Central Licensing Board till improvements in the said section and restoration by the Board.**

Case No. 02: CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.

Name of drug	Manufact-ured by	Declared by CDL as	Current Status of case	Decision of 291st Meeting of RB held on 02-04th September, 2019	Communication of Decision of 291st RB	Proceeding & Decision of 292ndmeeting of RB held on 01-02 Oct, 2019
1. Tabs. Paracetamol **Batch No.** 1595	M/s Pakistan Pharmaceutical and chemical Hyderabad	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of Paracetamol 500mg Tablet (Reg. No. 004251) for 2 months, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision of the Board was communicated vide letter no. 03-33/2009-DDC(QC-I) dated 10thAugust, 2012 and 29th	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			August, 2012 to the quarter concerned for its implementation.	status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

Response of FID vide letter no.F.SAA-001/2019-FID-V(K)(INV) dated 30th September, 2019:

"In compliance to decision of the Drug Registration Board undersigned along with Dr. Kirshan, Assistant Director, DRAP, Karachi visited the premises of M/s Pakistan Pharmaceuticals and chemicals, A-34, SITE, Hyderabad on dated 30th September, 2019 to ensure the implementation of the decision of the 234th Meeting of Drug Registration Board. During the course of the visit Mr. Sultan-ul-Haq Qureshi and Miss Maqsooda Begam (QC Incharge) were present at the premises, the manufacturing section of the firm was closed and it was observed that there was no any manufacturing activity being carried out for some time period, in addition there was no any record of said batch of paracetamol available at the premises of the firm and no any fresh stock of tablet paracetamol was available for re-sampling. The owner of the firm informed that they had never produced the said batch number (B.No. 10) of product paracetamol tablet and never received any letter pertaining to the said batch number from the DRAP, Islamabad / any concerned quarter."

Additional Director, DRAP, Karachi has been telephonically once again requested to send the implementation status before the meeting.

Proceedings and Decision of Board in its 293rd Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- That area FID be directed to again visit the firm and communicate the implementation of Board's decision of the case.
- The Board once again directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report:
    1. The area Additional Director, field office DRAP
    2. The area FID
    3. The area Assistant Director (I&E)

That the area FID shall submit a complete report including implementation status along with supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Karachi was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Karachi in the instant case.

Proceedings and Decision of Board in its 295th Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and submit complete report including implementation status along with supporting documents/evidences/ annexures/inspection reports within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

In response to the communicated decision of 293rd meeting of Registration Board, FID-V, DRAP, Karachi submitted reply vide No.F.SAA.001/2019-FID-V (K) (INV) dated 12th June, 2020 and is reproduced as under;

I have the honor to refer to the DRAP's letter no. F.03-65/2019-QC (293-RB) and this office earlier letter of even number dated 30 September, 2019 for the subject captioned above. In compliance of the directions passed by the Drugs Registration Board in its meeting no. 293, held on 06th - 08th January, 2020, the undersigned again visited the premises of M/s. Pakistan Pharmaceutical and Chemical Hyderabad on dated 04th June, 2020, the firm M/s. Pakistan Pharmaceutical and Chemical Hyderabad was found closed. Upon telephonic contact with the owner of the firm Mr. Sultan ul Haque Qureshi, he informed that currently he is on dialysis and the factory is closed these days and regarding telephonic discussion about the batch in question, he again informed that they had never produced the batch no. 10 of Paracetamol tablets and didn't receive any letter pertaining to the said batch number from DRAP, Islamabad or concerned quarter (the written response already submitted by the firm vide their letter of dated 30th September,2019 and the copy is enclosed herewith).

Decision of 295th meeting of Registration Board was communicated to the quarter concerned vide letter No.F.03-28/2020-QC (295th RB) dated 19-08-2020.

In response to the communicated decision of 295th meeting of Registration Board, FID-VIII, DRAP, Karachi submitted reply vide No.F.SY.004/2020-FID-VIII (K) dated 31st August, 2020 and is reproduced as under;

"*In compliance to the directions passed by the Drug Registration Board in its meeting No. 295th , held on 08-11th June, 2020 the undersigned visited the premises of M/s Pakistan Pharmaceutical and Chemical Hyderabad on dated 28th August, 2020.*

The firm was found closed due to sudden death of the owner of the firm Mr. Sultan Ul Haque Qureshi. Owner's son Asad Ul Haque Qureshi assured to comply with the decision of RB communicated vide letter No.F.SY.001/2020-FID-VIII (K) dated 26th August, 2020.

Furthermore, Factory was not operational and production was temporarily closed till 21st September, 2020 due to owner death. The written response of the firm is enclosed herewith.

Keeping in view of the facts stated above, the case may be placed and discussed in the Central Licensing Board under section 19(7) of Drug Act 1976 for further directions."

Proceeding and decision of the 296th meeting of Registration Board.

Registration Board after thorough deliberations constituted the following panel to conduct Panel inspection of the firm after 21st September for qualitative investigation of case (**Manufacture & sale of substandard Paracetamol tablets, Batch No.1595**) and submit a complete report including implementation status of 234th meeting of Registration Board's decision along with supporting documents/evidences/ annexures/inspection reports without waiting for the minutes of the meeting and for further consideration of the Board;

- **Dr. Rafeeq Alam Khan, Member Registration Board.**
- **Additional Director, DRAP, Karachi.**
- **Area Federal Inspector of Drugs, DRAP, Karachi.**

2. AB -Clor **Batch No.** D-173	M/s Alience Pharmaceuticals Peshawar	Sub-Standard and Adulterated	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of AB-Clor 250mg/5ml Suspension till the submission of stability data by the firm,	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case.	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office

			• Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide no.F.3-28/2009-QC-I dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation.	• The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		and place the case in forthcoming meeting of Registration Board.

Response of FID-II, DRAP, Peshawar vide No.F.11-54/19-Alliance-DRAP(P)-FID-II-6092:
"[…]The firm has submitted in reply that they appeared for personal hearing before the 234th DRB Meeting held on 23rd July, 2012.
3. The panel constituted vide letter no. F.3-28/2009-QC-I dated 29th August, 2012 conducted inspection on 05th and 26th December, 2013 wherein panel recommended restoring the production of the product.
Recommendation.
Therefore the panel recommends restoring the production of AB-Clor dry powder suspension as the firm has done sufficient improvements on the advice of the panel. (Copy of inspection report attached).
4. However there is no approval of Chairman, Registration Board available as per available office record.
5. Sampling of drug has also not been done as the firm has not manufactured the said product batches as per their letter no. 104-All/QC-19-20 dated 25th Sep, 2019. (Copy attached).

[…]"

6. As per company statement dated 25-09-2019 in the light of decision by DRB, despite recommendation by the panel regarding restoring the said product until now we have not manufactured the said product. However, no stability data is attached with the report.

Proceedings and decision of 293rd meeting of the Board

In the light of report submitted by FID, Peshawar, the board decided to verify the claims of the firm by corroborating it with import data of raw material required for manufacturing of product AB-Clor and place the case in forthcoming meeting of Registration Board. Aforementioned data shall be verified by DRAP, Peshawar.

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Peshawar was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020. Till now, no report has been submitted by the area FID, DRAP, Peshawar in the instant case.

Proceedings and Decision of Board in its 295th Meeting.

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter, to verify the claims of the firm by corroborating it with import data of raw material required for manufacturing of product AB-Clor and submit complete report within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

Current Status of the case.

That the Federal Inspector of Drugs, DRAP, Peshawar submitted his reply vide reference No.F.11-54/2020-Alliance-DRAP (P) dated 12-08-2020 regarding the subject of "Manufacturing And Sale Of Substandard And Adulterated Drug Ab-Color Batch No. D-173 – M/S Alliance Pharmaceuticals, Peshawar" addressed to the Director QA&LT, DRAP, Islamabad.

Wherein he has referred DRPS's Islamabad letter No.F.03-65/2019-QC (293-RB) dated 22-04-2020 and submitted that as per available office record of the firm M/s Alliance Pharma Peshawar has not imported API Cefaclor, the raw material required for manufacturing of product AB-Clor, since 2010. The same statement has also been submitted by the firm.

Proceeding and decision of 296th Meeting of Registration Board.

The Board after thorough deliberations, considering the facts of the case, report submitted by the FID, DRAP, Peshawar decided to issue show cause notice for cancellation/suspension of the subject cited drug to M/s Alliance Pharmaceuticals (Pvt.) Ltd., Peshawar.

3. Caps. Epoclox 500mg **Batch no:** 5A001	M/s Epoch Pharmaceuticals, Karachi	Substandard & Misbranded	As per available record of 219th Meeting of RB held on 20th August, 2009 wherein the case was presented before the Board and the Board after scrutiny of the record has decided to • Conduct CGMP inspection • Investigate the matter through a panel	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office

			• To draw the fresh samples. The decision vide letter No. F. 03-59/2006-QC dated 30-09-2009 communicated to the-then Deputy Director (QA) for its implementation.	with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		and place the case in forthcoming meeting of Registration Board.

Area FID, DRAP, Karachi vide no. F. 4-10/2019-FID-II-(K)1180 dated 04.10.2019 submitted as under:

"I have the honor to refer to your letter No.F.03-41/2019-QC (291-RB) dated 19th September, 2019 regarding subject cited above and to state that M/s Epoch Pharmaceuticals Karachi was contacted to clarify the subject matter.

2. The firm vide letter no. Nil dated 25th September 2019, submitted that the required inspection in that connection had been conducted by the then FID and Director CDL Karachi on 27th January 2010, but the sample of under referenced product was not taken for test & analysis.

3. It is further stated that as the necessary inspection has already been conducted thereby only samples were taken and sent to Federal Government Analyst, CDL Karachi for test & analysis in compliance to the direction.

4. All necessary documents in this matter are hereby attached for your information & further necessary action/direction."

Proceedings and decision of 293rd Meeting

Registration Board after detailed discussion and deliberations after considering the facts of the case decided as under:

"Directed area FID, Karachi to carryout Product (Caps. Epoclox 500mg) Specific Inspection for verification of root cause analysis, Corrective and preventive action (CAPA) by the firm and panel comprising of Dr. Rafeeq Alam Khan, Member Registration Board, Area FID and Ms. Hira Bhutto, AD-CDL.

Submit test/analysis report of already taken samples."

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Karachi was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020. **Till now, no report has been submitted by the area FID, DRAP, Karachi in the instant case.**

Proceedings and Decision of Board in its 295th Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and conduct Product (Caps. Epoclox 500mg) Specific Inspection for verification of root cause analysis, Corrective and preventive action (CAPA) by the firm and submit complete report with clear & candid recommendations within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

In response to the decision of 293rd meeting of RB, communicated vide letter No.F.03-65/2019-QC dated 22-04-2020 FID-II, DRAP Karachi forwarded the Product Specific inspection report vide reference No.F.000425/2020-FID-II (K) dated 14-07-2020. Inspection was conducted by Dr. Rafiq Alam, Area FID, DRAP, Karachi and Dr. Hira Bhutto Assistant Director, CDL, Karachi. Report is reproduced as under;

BACKGROUND:

M/s Epoch Pharmaceuticals (Byt) Ltd, situated at Plot 83-85 sector 15 Korangi Industrial Area Karachi was inspected on 1'5-07-2020 with reference to DRAP's letter no F. No. 03-65/2019 - QC(293RB)dated 22nd July, 2020in order to check the Rootcause of their substandard Epoclox 500mg capsule and subsequent corrective and preventive actions taken by them to avoid occurrence and recurrence of such failures in future.

Case Background.

i. *As per letter from deputy drug controller letter No. F. 4. 29.2003 QC the board in 219th meeting dated 20th August, 2009 constituted the panel for investigation of the matter comprised of Dr Tanver alam, Director CDL and Area FID and ADC. As per the report of panel the GMP report was unsatisfactory, (copy enclosed), however the samples of the product were drawn during inspection for test and analysis purposes and the results were of standard quality copy of the test report is annexed.*

ii. *As per Direction of registration board vide letter No F. 03-41/2019-QC (291-RB) dated 19th September, 2019 wherein area FID was directed to take Sapmples of Epoclox 500mg capsule for testing purpose. The area F.I.D took the samples of Epoclox 500mg capsule B # 010 on 25th September, 2019, the same were tested by central drug laboratory and the results found satisfactory as per CDL report dated 29th October, 2019 (Copy enclosed)*

iii. *The Board in its 293rd meeting held on 6th and 8th January 2020 directed area FID karachi to carry out product (caps Epoclox 500mg) specific inspection for verification of root cause analysis, corrective and preventive action of the firm by the panel comprising of Dr Rafeeq Alam khan, Member Registration Board, area FID and Ms Hira Bhutto AD, CDL*

The panel gone through following areas to identify the root-cause of above mentioned substandard product:

i. *Meeting / Discussion with technical staff*
ii. *Quality Control Department*
iii. *Production Section*
iv. *Raw Material Store*
v. *Documentation*

1 Meeting / Discussion with technical staff: *Before the start of inspection, the technical persons were interviewed and the background of the matter in question was discussed. Firm's representative told the panel that batch of Epoclox 500mg capsule B# 5A001 was manufactured in year February, 2005 currently no record of batch manufacturing or quality control testing available with firm however the copy of report of CDL dated 24th February, 2005 and investigation report of panel dated 27th January, 2010 available (copy enclosed).*

2. *Quality Control Department:*

- *No dedicated facility for testing of penicillin product available. The penicillin products were tested in general quality control Lab.*
- *The record showed that product was tested as per In-House specifications, however no record of*

product testing of Epoclox 500mg Capsule B # 5A001 available.

- *Calibration of most of the equipment in quality control lab was due for which no updated schedule for calibration available.*
- *the documents record / log sheets and record of relevant raw calculation was found to be un-satisfactory and non-traceable.*
- *Analytical method validation or verification of raw material and finished pharmaceutical product not available.*

3. *Raw Material Store:*

The raw material store, storage conditions and relevant supporting documents / log sheets were reviewed.

- *Uncontrolled material storage area was provided within segregated facility of Penicillin*
- *Cleaning condition of raw material store was unsatisfactory.*
- *Job description of dispensing pharmacist was not available. Dispensing pharmacist is directly reporting to CEO.*
- *No dedicated staff for penicillin production facility. The firm have only one dispensing pharmacist who perform the dispensing operation of penicillin and non-penicillin products*
- *Raw material was not assigned unique identity code at the time of arrival. Raw material details could not be traced from material issuance note as no unique code assigned*
- *Dispensing booth is not of adequate size to perform dispensing operations*

4. *Production Section:* *Technically the penicillin manufacturing areas were not dedicated on the following grounds.*

- *The entrance to the area was provided through a common entrance from general area.*
- *Area classification and qualification was not justified*
- *HVAC of area was unfunctional, return ducts were provided on roof*
- *HVAC qualification record not available*
- *Current status of penicillin area is not as per provided lay out plan*
- *No area for in process checks control available.*
- *Machine parts of penicillin were placed in tool room of general area*
- *Primary packaging of capsule in jar performed in uncontrolled area*
- *batch manufacturing formula, production equipment, log books, equipment and relevant SOPs were checked and found a satisfactory level of compliance.*

5. *Documentation:*

- *Batch manufacturing record of Epoclox 500mg capsule B# 010 manufactured in August, 2019 was reviewed by panel. Batch was manufactured as per standard BMR. The product testing record of that batch was also reviewed. The batch was tested as per In House specifications,*
- *Equipment calibration and dispensing booth calibration records were reviewed*
- *No cleaning validation record available*
- *Log books were uncontrolled without specific code and page numbering*

Findings of inspection.

- *Product validation of Epoclox 500mg capsule were not performed.*
- *The firm change the primary packaging of epoclox 500mg from strip to jar without performing stability studies and without necessary regulatory approval.*
- *The Material issuance note of Epoclox 500mg capsule B # 010 shows that cioxacillin sodium USP grade was used however COA of manufacturer shows that the raw material tested as per BP grade. The firms representative said it is a documentation error.*
- *Batch documents have no recording of time of production steps.*
- *Incident report, deviation form and CAPA not raised for this incident*
- *SOP of CAPA SOP # EP/QA/SOP-010/002 were implemented on 11-11-2019 have no description of CAPA investigation committee firm advised to review this SOP.*
- *SOP of documentation control not available.*
- *No CAPA and incident report of Epoclox 500mg capsule B # 5A001 was available*
- *As per material issuance record of raw material (Bin card) no standard batch sizeof Epoclox 500mg capsule is followed batches are manufactured as per market demand.*
- *The batch manufacturing record of Epoclox 500mg capsule B # 009 and 010 were available and reviewed. As per the record of batch #010 weight variation in capsule were observed most of the capsule were filled below lower limit (limit 670mg to 700mg)*
- *Batch # 009 weight variation limit is 656mg to 725mg. no standard limit is followed.*
- *Change control mechanism and documents were not available*

Details of previous/subsequent batches is described as under: Detailed record of manufacturing and testing were

not available however as per material issuance BIN card following details has been recorded.

S No:	Product name	Batch No	Date Of dispensing of raw material	Packaging Detail
1	Epoclox 500mg	006	31-08-2012	Jar Packaging
2	Epoclox500mg	007	19-08-2014	Jar Packaging
3	Epoclox 500mg	008	22-12-2016	Jar Packaging
4	Epoclox500mg	009	02-02-2017	Jar Packaging
5	Epoclox500mg	010	08-08-2019	Jar Packaging

Conclusion / Recommendation:

In the light of the meeting with staff, documents review including manufacturing, testing and ware-house record and findings of the inspection, the firm has been found non-compliant in so called dedicated manufacturing facilities of Penicillin. Based on the stated observations the panel unanimously recommends as follows.

Suspension of manufacturing activities in Penicillin areas till the rectifications of all critical observations stated in the report.

The Panel also recommends suspension of subject product till the submission of product development data and re-verification of the same by a panel.

All the findings raised during inspection were discussed in detail with the representatives of the firm and they agreed to overcome those findings within four months. Further they agreed to suspend their production activities in penicillin department till the rectification of observations raised by the panel.

It is submitted that the fresh samples of epoclox capsules, B#010, taken for the purpose of test/analysis have been declared as of Standard quality by the CDL, Karachi vide test reportNo.KQ.422/2019 dated 29-10-2019.

Proceeding and Decision of 296th meeting of Registration Board.

The Board after detailed deliberations, considering the inspection report forwarded by the panel constituted by the Board in its 293rd meeting decided as follows;

- **QA&LT Division shall process the panel report by its own, as per their prescribed procedure without waiting for the minutes of the 296th meeting of Registration Board.**
- **Registration Board also recommended the suspension of the Penicillin (Capsule) section to the Central Licensing Board till improvements in the said section and restoration by the Board.**

4.Inj. Neutim 250mg **Batch No.** 0265P061	M/s Neutro Pharma (Pvt) Ltd; Lahore.	Substandard	As per available record the case was presented in 228th Meeting of RB held on 12 & 13th October, 2010 wherein the Board decided as under: • strict warning to the firm. • Panel GMP inspection • Sampling of the raw material.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the

				with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		case in forthcoming meeting of Registration Board.

The Additional Director, DRAP, Lahore vide no. 16078/2019-DRAP(L-VI) dated 04.12.2019 informed that the inspection of M/s Neutro Pharmaceuticals, 9.5-Km Sheikhupura road, Lahore was conducted by the panel of inspectors on 02.10.2019. The conclusion of said report is reproduced as under:

"**Conclusion**:
In the light of above the panel has given some advises regarding GMP compliance and also observed that the firm is not manufacturing drug namely Neutim 250mg injection since last 7-8 years. No manufacturing record was available of the above said drug even no any raw material was available for sampling of the said product at the time of visit, so it is suggested that the registration of the said product Neutim 250mg Injection Registration No. 038852 may be suspended/ cancelled as the management also discontinued this drug since 7-8 years due to its unavailability of demand in local market (copy of firm's Reply attached) on the other hand, the firm GMP practices was found satisfactory and few shortcomings were noticed and communicated to the firm representative for immediate compliance and also asked for their compliance report as stated above"

It is proposed that as identified in the report, the firm is not manufacturing drug namely Neutim 250mg injection since last 7-8 years, so the registration of the said product may be withdrawn/cancelled as per prevailing law.

Proceedings and Decision of 293rd Meeting

Board after detailed discussion and deliberations after considering the facts of the case decided to issue show cause notice to the firm/responsible persons for cancellation/suspension of Registration of Neutim 250mg injection as recommended by the panel in inspection report dated 02-10-2019. The board Further decided to verify the claims of the firm by corroborating claim of not producing it with import data of raw material from DRAP Lahore required for manufacturing of product Neutim Injection and place the case in forthcoming meeting of Registration Board.

- The FID, DRAP, Lahore was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Lahore in the instant case.

Proceedings and Decision of Board in its 295th Meeting.

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and to verify the claims of the firm by corroborating claim of not producing it with import data of raw material from DRAP Lahore required for manufacturing of product Neutim Injection & submit report with clear and candid recommendations within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

Current status of the case.

In response to the show cause notice issued as per decision of the Registration Board in its 293rd meeting, M/s Neutro Pharma (Pvt.) Ltd., submitted their reply vide reference No. nil dated 11-04-2020 and is reproduced as under;

"This is with reference to your letter No. F.03-65/2019-QC (293-RB), dated 22nd April, 2020 (copy enclosed), regarding our said product about your proposal after re-inspection ***"that as identified in the report, the firm has not manufactured drug namely Neutim 250 mg since last 7-8 years, so the registration of the said product may be withdrawn/cancelled as per prevailing law".***

This issue happened in 2005 when Neutro Pharma was newly established. Since then we are improving quality of our products in a continuous way. We have upgraded our equipment, system and QC lab to improve and ensure product quality and safety.

Regulatory authorities have visited our premises multiple times since then and have been granted/renewed our GMP and DM License after thorough panel inspections with satisfactory remarks. Besides, none of our products have been declared substandard or adulterated since 2005.

In the last GMP inspection of our manufacturing plant, inspection team gave us good level of grading and our organization was ranked at "low risk".

We are committed to produce quality products and improvement in quality standards of our products is our prime objective. ***We request you not to cancel registration or take any other action against us and we also assure you that we'll manufacture this product whenever there is market demand****.*

Furthermore, we assure you that we are taking rigorous checks and testing our products to make sure that only products of standard quality are produced and authorized for marketing.

Please, accept our request."

It is submitted that decision of the 295th meeting of Registration Board was communicated to the Area FID, DRAP, Lahore vide letter No.F.03-28/2020-QC (295th RB) dated 19-08-2020 with request to comply with the decision of Registration Board.

The additional Director, DRAP, Lahore vide reference No.12290/2020-DRAP (L-VI) dated 31-08-2020 has forwarded the report in response to the above said letter and is reproduced as under;

"Panel inspection of M/s Neutro Pharma, Lahore was conducted with reference to Drug Regulatory Authority of Pakistan, Islamabad letter No.F.03-41/2019-QC (291-RB) dated. 19-09-2019, on 02-10-2019 to chock cGMP compliance status of die dry powder injectable section of the firm. The panel concluded that:

In the light of above the panel has given some advises regarding GMP compliance and also observed that the firm is not manufacturing drug namely Neutim 250mg injection since last 7-8 years. No manufacturing

record was available of the above said drug even no any raw material was available for sampling of the said product at the time of visit, so it is suggested that the registration of the said product Neutim 250mg Injection Registration No. 038852 may be suspended/ canceled as the management also discontinued this drug since 7-8 years due to its unavailability of demand in local market. On the other hand, the firm GMP practices was found satisfactory and few shortcomings were noticed and communicated to the firm representative for immediate compliance and also asked for their compliance report as stated above"

Panel inspection of M/s Neutro Pharma, Lahore was conducted with reference to Drug Regulatory Authority of Pakistan, Islamabad letter No.F.03-65/2019-QC (293-RB) dated 22-04- 2020 and even No. dated 02-06-2020, and letter No. 03-28/2020-QC (295-RB) dated 19-08-2020 received 21-08-2020, to verify the claim of the firm of not producing Neutim Injection 250mg and corroborating that claim with import data of raw material from DRAP, Lahore required for manufacturing of the said product, as decided by the Drug Registration Board in its 293rd and 295th meetings conducted on January 06-08th January, 2020 and 08-11th June, 2020, respectively.

As per available record of this office the firm had imported total 140kgs of Ceftazidime Pentahydrate raw material from Year 2016 to Year 2019. Detail is as follows;

Import date	***Quantity imported***
January, 2016	*60*
July, 2017	*30*
November, 2017	*30*
April, 2019	*20*

As stated by tire firm's management, the imported material had been used in the manufacturing of Injection Neutim 500mg and 1gm and Ceftebas Injection 1gm. ***Ceftebas Injection 1gm is registered for export purpose only.*** *The same was verified from raw material stock ledger of the firm. During the inspection, the firm's management also informed the panel that the firm is engaged in toll manufacturing of M/s Mega Pharma for Injection Megtazidime (Ceftazidme) 250mg and 1gm.*

However, at the time of inspection no raw material (Ceftazidime) was available at the premises and the stock in hand was nil. The same was also verified from the raw material ledger. Moreover, inventory of labels of Neutim Injection 250mg was Nil as of 01/12/19. The inventory of Neutim 250mg Injection was 9750.

Conclusion:

In light of the above, and on the basis of documentation reviewed, the panel observed that the firm is not manufacturing Neutim Injectio 250mg (Registration No. 038852) since last 7-8 years, as communicated by the firm earlier as well. However, the firm has used the imported 140kgs Ceftazidim raw material in the manufacturing of Neutim 500mg, 1gm and ceftebas injection for export only and Megtazidime injection 250mg and 1gm for M/s Mega Pharma. Submitted for necessary action and further deliberations by the Board, please.

Proceeding and decision of the 296th Meeting of the registration Board.

Mr. Abdul Hafeez, Regulatory manager of M/s Neutro Pharma, Lahore appeared before the Board on behalf of M/s Neutro Pharma to plead the instant case. He submitted that personal hearing letter was received to them on 10-09-2020 and requested to kindly give them another opportunity of personal hearing, so that their technical person can explain the case.

Decision of the 296th Meeting of Registration Board.

The Board after considering the facts of the case, request of the firm and after thorough deliberations decided as follows;

- **Suspended the Registration of the Neutim 250mg Injection Registration No. 038852.**
- **Acceded the request of the firm and give them another opportunity of personal hearing to the firm.**

Name of drug	Manufact-ured by	Declared by CDL as	Current Status of case	Decision of 291st Meeting of RB held on 02-04th September, 2019	Communication of Decision of 291st RB	Proceeding & Decision of 292ndmeeting of RB held on 01-02 Oct, 2019
5. Isotop 20 mg Capsule **Batch No.** 003	M/s Panacea Pharmaceuticals, Islamabad	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under:	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further

			• Suspension of registration of Isotop 20mg Capsule (Reg. No. 0054948) for 2 months, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide **No. F. 3-46/2010-DDC (QC-I)** dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation. **That the area FID-II, Islamabad vide letter No. 3-12/2004-FID-I(ISD) dated 29th January, 2013 informed panel inspection has been conducted on 23.01.2013**	communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			and forwarded the copy of panel inspection report. The conclusion is as under: "the panel recommended that the firm may be allowed manufacturing of a trial batch with approved source of M/s Taizhou Tlanrui Pharmaceutical, China for conducting the stability studies and submission of the results to the registration Section. Later on the sample could be taken for the testing of the product from the Central Drug Laboratory Karachi. the Resumption of production of ISOPTOP Capsule (Isotretinoin) shall be granted after satisfactory report from the CDL Karachi" That the-then ADC(QC) vide letter No. F. 3-46/2010-DDC (QC-I)dated 14th February, 2013 conveyed the **approval granted by Chairman, Registration**			

			Board for manufacturing of trial batch of ISOTOP Capsule by utilizing approved source of M/s Taizhou Tlanrui Pharmaceutical, China for conducting stability studies and proceeding further as per recommendations of the panel. That FID-II, Islamabad vide letter no. 3-12/2004-FID-I(ISD) dated 12th November, 2013 forwarded report test/analysis report of CDL Karachi wherein the CDL, Karachi declared the trial batch sample taken by FID from firms' premises as **MISBRANDED** for not mentioning the retail price on outer carton as required under law. That the FID-II, Islamabad pertinently mentioned that the tiral batch sent for the purpose of analysis on the direction of Registration Board the firm was not allowed to sell			

			the batch in the market.			

FID-III, DRAP, Islamabad vide no. F. 03-12/2004-FID-I(ISD) dated 30th September, 2019 submitted as under:

"Please refer to Assistant Director (QC) for Secretary, Registration Board letter No. 3- 41/2019-QC (291 -RB) dated 19-09-2019 on the subject cited above and to say that the following panel have inspected M/s Panacea Pharmaceuticals. Plot No. 4, Street No S-6. National Industrial Zone. Rawat on 25-09-2019 to comply with/ enforce the Board's decision in its letter and spirit.

i. Dr. Hafsa Karam Elahi, Add. Director (QA & LT), DRAP, Islamabad
ii. Dr. Hasan Afzaal, FID-II, DRAP, Islamabad
iii. Dr. Qurat Ul Ain Jamil Rana, Assistant Director (I&E), DRAP, Islamabad"

Conclusion of the report is reproduced as under:

"Keeping in view all the above stated facts under consideration, the panel has opined that the implementation of the Decision of the Drug Registration Board in its 234th& 291stMeetings was implemented with a slight variation in the "resumption of production will be after satisfactory inspection report of panel and approval of Chairman, Registration Board"; The spirit of the decision has been upheld since the product was suspended for a period for not less than two (02) months, the panel inspection of the firm for qualitative investigation of case was carried out, conditional resumption for manufacturing trial batch was granted by the Chairman Registration Board, and subsequent sampling was performed; although the sample was declared as misbranded (based on the reason that the product did not have MRP printed, as the product was trial batch, but the Form-4 had no mention of this information) by the Federal Government Analyst from CDL Karachi, nevertheless the product complied the requisite limits based on the Assay for Isotretinoin. However, the firm was not given a formal approval for the manufacture of commercial batches of the product Isotop 20 mg Capsule"

It is apprised that FID-III, Islamabad took following samples during aforesaid inspection:

Name of Product	Manufactured by	Registration #	Batch #	Mfg date	Exp Date
Isotop 20 mg Capsule	M/s. Panacea Pharmaceuticals, Plot# 4 Street #S-6, National Industrial Zone, Rawat, Islamabad	054948	069	09-18	09-19
Isotop 20mg Capsule	-do-	054948	072	07-10	07-20

FID vide letter no. F.03-12/2004-FID-I(ISD) dated 18th December, 2019 informed that the Federal Government Analyst CDL, Karachi under section 22 of the Drugs Act, 1976 has submitted the test reports of above mentioned drug batch No. 072 declared as "Standard" quality vide Test Report No. IP. 109/2019 dated 11thOctober, 2019 and batch No. 069 was returned back from CDL Karachi due to short expiry date.

Furthermore, FID order not to dispose of following stock at M/s Panecea Islamabad.

Sr.	Name of Drug	B.No. & Quantity	Manufacturer	Reason
01.	ISOTRFETINOIN POWDER	1904017 5kg	M/s Shanghai New Hualian Pharmaceutical Co. Ltd	The product is usnder investigation in compliance to the letter No.F.03-41/2019-QC (291-QC)

FID-III, Islamabad vide letter of even number dated 17-10-2019. M/s. Panacea has requested to please allow the use of raw material Isotretinoin powder for manufacturing of registered products as CDL, Karachi has already declared the above mentioned drug as of standard quality.

Proceedings and Decision of 293rd Meeting of the Board:

The Board after detailed discussion and deliberations after considering the facts of the case decided as under:

a. Suspended the Registration of product of Isotop 20 mg Capsule issued in favor of M/s. Panacea Pharmaceuticals, Plot# 4 Street #S-6, National Industrial Zone, Rawat till further orders; and
b. to give personal hearing to M/s Panacea Pharmaceuticals, Plot# 4 Street #S-6, National Industrial Zone, Rawat in upcoming meeting of Registration Board.

In compliance with the decision of the Board, the Decision has been communicated to the quarter concerned vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020.

However, in the prevalent situation of COVID-19 the personal hearings letters were not issued for 295th meeting of registration Board.

M/s Panacea Pharmaceuticals vide reference No. nil dated 15-07-2020 submitted that Mr. Hassan Afzaal Area FID-III visited our premises Panacea Pharmaceuticals along with Dr. Qurat Ul Ain Jamil Rana and withdraw samples of our registered product lsotop 20mg Capsule Batch # 069 & 072 for the purpose of Analysis.

During that visit of our premises DRAP's Officials also sealed Isotretinoin (5.00kg) active material; we were using for manufacturing of both Isotop 20mg Capsule & Isotop Gel 0.05% (Reg. No. 075032) and advised us not to dispose of said material as product is under investigation.

Now after clearance of our product **(declared** as of **"standard quality")** from CDL Karachi, it is our request that please allow us to use material Isotretinoin for manufacturing of our registered product Isotop Gel 0.05%.

Proceeding and decision of 296th meeting of Registration Board.

Mr. Abid Hussain (12103-5720698-1), Production Manager & Mr. Qamar abbas (13302-9893508-5), Quality Control Manager of M/s Panacea Pharmaceuticals, Rawat appeared on behalf of M/s Panacea Pharmaceuticals to plead the instant case. They informed that they are manufacturing Isotop capsule in Hard Gel. They further requested to allow them to use the raw material of Isotretinoin in the manufacturing of Isotop Gel 0.05% (Reg. No. 075032)

Decision of 296th Meeting of Registration Board.

The Board after considering the facts of the case, request of the firm and thorough deliberations decided as follows;

- **The firm shall revise their formulation as per innovator product i.e., "Absorica capsules approved by US FDA"**
- **Scientifically rationale lab scale product development & stability data shall also be submitted along with requisite documents as decided by Registration Board in its 293rd meeting against the case title "Requirements for Stability study data and exemption from onsite inspection".**
- **Sampling of the Active Pharmaceutical Ingredient by the Area FID for test/analysis from Central Drug Laboratory, Karachi. The firm can use the API for manufacturing of their product Isotop Gel 0.05% (Reg. No. 075032) only, if the test/analysis report from CDL, Karachi is of standard quality.**

6. Susp. Amocilline DS **Batch No.** K229	M/s CCL Pharmaceutical (Pvt) Ltd; Lahore.	Substandard	The case was presented in 214th DRB held on 29.10.2008 After detailed scrutiny the Board decided to drop the case with directions to the firm to rectify the problem. The same was communicated vide letter No. 03-326/07-QC dated 20.11.2008	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

				3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

The Additional Director, DRAP, Lahore vide no. 13460/2019-DRAP(L-VII) dated 21.10.2019 informed that the inspection of M/s CCL Pharmaceuticals, Lahore was conducted by the panel of inspectors on 10.10.2019 to verify the manufacturing and sale of Susp. Amocilline DS Batch No. K229. The observations and conclusion of said report is reproduced as under:

"[…]2. The firm's management informed the panel that they had discontinued the manufacturing of Amocilline DS Suspension in March 2007. Later, during inspection by the then area FID on 27-06-2012, it was highlighted that the firm did not have segregated / dedicated facility/section for manufacturing of penicillins. The firm's management informed that they agreed to withdraw the registration of 15 penicillin-containing products as they did not have the requisite section. (Copy attached).

3. Firm's management informed the panel that they have applied for de-registration of the afore-mentioned 15 products, including Amocilline DS Suspension (No evidence was provided).

4. Accordingly, firm did not have any penicillin raw material, in warehouse or finished goods containing penicillin at the premises at the time of inspection. No retaining samples, BMR, testing documentation related to Amocilline DS Suspension were provided by the firm.

5. However, the firm was advised to ensure compliance to Drugs Labeling and Packaging Rules 1986 for all its registered products.

Conclusion

In view of the above observations, the panel could not verify testing, raw material status, documentation, BMRs, production facility for Amocilline DS Suspension, Batch No. K229, as the firm did not have any record/retaining samples of the said product."

It is proposed that as identified in the report, the dedicated facility for penicillin product is not available with the firm and they discontinued the product Amocillin DS, so the registration of the said product may be withdrawn/cancelled as per prevailing law.

Proceedings and Decision of 293rd Meeting

Board after detailed discussion and deliberations after considering the facts of the case decided to issue show cause notice to the firm for cancellation/suspension of Registration of Amocilline DS Suspension issued in favor of M/s CCL Pharmaceuticals, Lahore.

In compliance with the decision of the Board, the Decision has also been communicated to the quarter concerned vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020.

"In response to the above said show cause notice, M/s CCL Pharmaceuticals (Pvt.) Ltd., submitted their reply and is reproduced as under;

Please refer to your letter no. F.03-65/2019-QC (293-RB) dated 22nd April, 2020 regarding captioned subject.

We would like to emphasize that:

- It has already been intimated to the panel of inspectors during their visit to our plant on 10.10.2019 that we had discontinued the said product since 2007.
- We had surrendered the registration of penicillin containing products (12) on 25.06.2011 against "Registration of Drugs on Fast Track Basis" for new registration applications; as per DRB policy at that time.
- Accordingly, we have not applied for the renewal of registration of said product, due to non-availability

of dedicated manufacturing facility.

As per decision of DRB in its 293rd meeting, we have no objection for cancellation of registration of subject drug as per prevailing law. We will appear before the worthy board to explain the position, if so desired. We would like to assure you that no provision of the Drugs Act, 1976 and rules there under has been violated by CCL Pharmaceuticals (Pvt.) Ltd. in any way at any time.

Thanking you and assuring you our best compliance & cooperation all the times, we remain."

Proceeding and Decision of the Registration Board.

Mr. Imran Babar (33100-6771955-7), SMCA of M/s CCL Pharmaceuticals, Lahore appeared before the Board on behalf of M/s CCL, Pharmaceuticals, Lahore to plead the instant case. He submitted that CDL, Karachi declared the said product as of substandard quality. Method of analysis adopted by CDL, Karachi does not comply with manufacturer provided method of analysis, therefore, they applied for retesting from NIH, Islamabad. NIH, Islamabad declared the said sample as Misbranded on the basis that the firm has not printed Pharmacopoeial or Manufacturer's specifications for the dosage form and instruction & method of reconstitution is printed in English & Urdu version on outer packing while on immediate packing it is only in Urdu version. On the basis of report of NIH, Islamabad as the product is of standard quality, therefore it is requested to correct the record. He further submitted that they have no objection on the cancellation of the said product. However, at the time of test/analysis CDL, Karachi have not applied their protocols.

Decision of 296th Meeting of the registration Board.

The Board after considering the facts of the case and thorough deliberations decided to cancel the Registration of Amocilline DS Suspension Reg. No. 008923.

AGENDA ITEM NO. 02: NEW / ONGOING QC CASES

Case No.01: MANUFACTURE & SALE OF SUB-STANDARD ZANCPAL SUSPENSION, BATCH NO. D281 BY M/S ZANCTOK PHARMACEUTICAL LABS, HYDERABAD.

The Federal Inspector of Drugs-V, DRAP, Karachi visited the premises of M/s National Institute of Child Health (NICH), Rafiquee Shaheed Road, Karachi, on 26-07-2018 wherein the sample of Zancpal Suspension, Batch No. D281, manufactured by M/s Zanctok Pharmaceutical Labs, Hyderabad was drawn under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976 for the purpose of test/analysis. Details are as under;

Name	Zancpal Suspension
Composition	Each 5ml contain 120mg Paracetamol
Registration No:	008351
Batch No:	D281
Manufacturing Date:	02-18
Expiry Date:	01-20
Claimed Manufacturer:	Zanctok Pharmaceutical Labs, Hyderabad

Portion of the sealed sample was sent to Federal Government Analyst, Central Drug Laboratory, Karachi vide memorandum No.SAA-47-48/2018-FID-V (K) dated 27-07-2018.

Portion of the sealed sample was also sent to DRAP, Islamabad under section 19 of the Drugs Act, 1976 vide memorandum No.SAA-47-48/2018-FID-V (K) dated 27-07-2018.

The Federal Government Analyst, CDL, Karachi declared the above mentioned sample as of substandard quality vide test/analysis report No. KQ.548/2018, dated 08th August, 2018. Results of the test report of CDL, Karachi are reproduced as under:

Description: *Blackish pink colored suspension in ambered glass bottle.*
Manufacturer's Description: *Pink colored suspension* ***(Does not comply with description)***
Identification: *Paracetamol identified.*
Assay for Paracetamol:
Determined amount/5ml: *77.4787mg*
Stated amount/5ml: *120mg*
Percentage: *64.6%*
Limits: *90.0% to 110.0%* ***Does not comply.***
Remarks:- *The sample is of* ***" substandard"*** *quality under the Drugs Act. 1976.*

The firm didn't agree to the results of CDL, Karachi and requested for retesting under Section 22(4) of the Drugs Act, 1976 and rules framed there under. On the request of the firm, the Board's portion of the sample was sent to Appellate Laboratory, NIH, Islamabad for retesting vide No.F.03-69/2018-QC dated 18-03-2019 under section 22 of the Drugs Act, 1976.

The Appellate Laboratory, NIH, Islamabad vide their test report No.011-M/2019 dated 23rd April, 2019 has also declared the said sample as of substandard quality. Test results of the NIH, Islamabad are reproduced as under:

Description: *Four bottles of Zancpal suspension received and their description is as below:*
Bottle 1: *Pink colored suspension in an amber colored glass bottle with white plastic cap. The suspension also contains black particles.*
Bottle 2: *Pink colored suspension in an amber colored glass bottle with white plastic cap.*
Bottle 3: *Pink colored suspension in an amber colored glass bottle with white plastic cap.*
Bottle 4: *The cap of the bottle is found broken and found empty.*
Does not comply with manufacturers specifications which describes the Zancpal suspension as "A pink colored thick suspension with raspberry flavour"

Identification: *Paracetamol identified.*

Volume:	***Determined:***	***Limit:***
Bottle1:	*60ml*	*60ml*
Bottle2:	*55ml*	*60ml*
Bottle3:	*60ml*	*60ml*
Bottle4:	*Empty*	*Empty*

(Does not comply with volume stated on the label)

Determined: *45.49% of the labeled amount.*
Limit: *Not less than 75%(Q) of the labeled amount.*
Does not comply with USP 39.

Assay for Paracetamol:	***Stated***	***Found***	***Limit***	***Percentage***
Bottle 1 Paracetamol: ***(Pink colored suspension)***	*120mg/5ml*	*114mg/5ml*	*95-105%*	*95.0%*
Bottle 2 & 3 Paracetamol: ***(Black colored suspension)*** ***(Does not comply withBP-2017)***	*120mg/5ml*	*58.43mg/5ml*	*95-105%*	*48.69%*

In the opinion of the undersigned the sample is of substandard quality as defined in the Drugs Act, 1976 for the reason(s) given below:

Description: *Four bottles of Zancpal suspension received and their description is as below:*
Bottle 1: *Pink colored suspension in an amber colored glass bottle with white plastic cap. The suspension also contains black particles.*
Bottle 2: *Pink colored suspension in an amber colored glass bottle with white plastic cap.*
Bottle 3: *Pink colored suspension in an amber colored glass bottle with white plastic cap.*
Bottle 4: *The cap of the bottle is found broken and found empty.*
Does not comply with manufacturers specifications which describes the Zancpal suspension as "A pink colored thick suspension with raspberry flavour"

Identification: *Paracetamol identified.*

Volume:	***Determined:***	***Limit:***
Bottle1:	*60ml*	*60ml*
Bottle2:	*55ml*	*60ml*
Bottle3:	*60ml*	*60ml*
Bottle4:	*Empty*	*Empty*

(Does not comply with volume stated on the label)
Determined: *45.49% of the labeled amount.*
Limit: *Not less than 75%(Q) of the labeled amount.*
Does not comply with USP 39.

Assay for Paracetamol:	***Stated***	***Found***	***Limit***	***Percentage***
Bottle 1 Paracetamol: ***(Pink colored suspension)***	*120mg/5ml*	*114mg/5ml*	*95-105%*	*95.0%*
Bottle 2 & 3 Paracetamol: ***(Black colored suspension)*** ***(Does not comply withBP-2017)***	*120mg/5ml*	*58.43mg/5ml*	*95-105%*	*48.69%*

Remarks: *1. Variation in cooler of suspension is observed in the same batch of zancpal suspension as one bottle is pink colored suspension whereas other bottles have black colored suspension.*
2. The label of the bottles of zancpal suspension is badly damaged and the particulars regarding Registration No., License No., date of manufacturing, date of expiry, Batch No., manufacturer, dosage and directions are not legible.

Conclusion: *The sample is of substandard quality on the basis of tests performed.*

Federal Inspector of Drugs-V, DRAP, Karachi provided that keeping in view of the test reports of CDL, Karachi and NIH, Islamabad the firm has violated Section 23(1)(a)(v) of the Drugs Act, 1976 and also provided the following names:

i. M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
ii. Mr. Muhammad Saleem (Partner).
iii. Mr. Wazir Ali Lasi (Partner).
iv. Ms. Shabana Yousuf (Production Manager)
v. Ms. Salma Bibi (QC Incharge)

The Drugs Licensing Division was requested to verify/provide the names provided by the FID-V, DRAP, Karachi and they provided the following;

M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Muhammad Saleem **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Wazir Ali Lasi **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Salma Bibi **(Q.C Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Shabana Sadiq **(Production Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	

Show cause notice was issued to the firm and above accused, along with the copies of CDL, Karachi & NIH, Islamabad test reports, under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-69/2018-QC dated 21-04-2020 for the following actions.

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

In response to the above said show-cause notice the firm has replied as under;

"1. Sample of subject cited drug was taken from the premises of M/s. National Institute of Child Health (NICH), Rafique Shaheed raod, Karachi on 26 July 2018 for analysis purpose by the FID-V DRAP and Karachi.

2. No sealed portion or intimation of sample taken was sent to manufacturer.

3. The Federal Government analyst CDL Karachi declared the above-mentioned samples substandard quality vide test / analysis report No. KQ.548/2018 dated 8 August 2018. Manufacturer was informed through FID vide letter No. FSAA-07-15/2018-FID-V(K) dated 15 August 2018. Report stated 64.1% efficacy and in description column mentioned blackish pink colored suspension filled in amber glass bottle along with providing all details including name of product, batch no, name of manufacturer etc. details were taken from form no. 4 / label.

4. In response to FID No. FSAA-07-15/2018-FID-V(K) dated 15 August 2018 manufacturer rigorously investigated and came to decision that NICH did not comply with storage conditions. Therefore, the manufacturer requested FID to retest the samples through National Institute of Health (Appellate laboratory).

5. National Institute of Health (Appellate laboratory), Islamabad declared four sample bottles substandard vide its test report no. 011-M/2019 dated 23 April 2019. The details of which is as under; Hence the sample were declared substandard from NIH, but it confirmed our investigation that due to noncompliance of proper storage conditions. It was also mentioned in NIH report that the labels of the Zancpal suspension bottles were badly damaged and the particulars including registration number, license number, date of manufacturing, date of expiry, batch number, dosage and directions are not legible.

We supplied 60 batches of Zancpal suspension to different institutions and their samples were also tested, but never found any problem (testing reports of different batches attached).

We have gone through the batch record that fo not reveal any discrepancy throughout the production cycle include dispensing, manufacturing, IPC, analysis, packaging and dispatching.

Retention samples found to be ok well within the specification.

We hereby confirm that we maintained GMP compliance (cGMP audit report attached).

We have ISO 9001:2015 "Quality management system" certificate. Our plant is regularly visited by auditors of Quality management system to assure quality standards.

Based on all above facts, we had presented all the facts and finding in this regard.

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. M. Fahim (42101-0117271-9), Regulatory Manager of M/s Zanctok Pharmaceutical labs, Hyderabad appear before the Board on behalf of M/s Zanctok Pharmaceutical to plead the instant case. He submitted that the report of NIH confirmed that the substandard results of our product were due to improper storage conditions. Improper storage condition are also supported by the fact that construction work was carried out at NICH at the time of sampling of the said drug. He further added that they have manufactured over 60 Batches of the said product and all of them were according to the specifications.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL & NIH, Islamabad decided as under:

i. **Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis, Corrective and preventive action (CAPA) by the firm, product development data and verification of aforementioned points and Product Specific Inspection by following panel whichever is later.**
   - **Dr. Rafiq Alam Khan, Member Registration Board.**
   - **Additional Director, DRAP, Karachi.**
   - **Area Federal Inspector of Drugs.**

Case No.02: MANUFACTURE & SALE OF SUB-STANDARD KEYGESIC 75 TABLETS, BATCH NO. 2918 BY M/S BENSON PHARMACEUTICALS, ISLAMABAD.

The Federal Inspector of Drugs-II, DRAP, Peshawar visited the premises of M/s Haider Zaman Medicose, near DHQ Hospital, Charsadda on 17-09-2018 wherein the sample of Keygesic 75 Tablets, Batch No. 2918, Manufactured by M/s Benson Pharma, Islamabad was drawn under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976 for the purpose of test/analysis. Details are as under;

Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Purported to be manufactured by.
Keigesic-75 Tablets	021577	2918	01-18	01-21	M/s Benson Pharmaceuticals, Rawat

The said sample was sent to the Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.F.10-124/2018-Haider Zaman Medicose, DRAP-3564 dated 18-09-2018.

The Federal Government Analyst, CDL, Karachi vide their test report No.IP.273/2018 dated 17th October, 2018 declared the above said sample as of substandard quality. Test results of the CDL, Karachi are reproduced as under:

Description: *Brown colored, circular biconvex film coated tablets*
Identification: *Diclofenac Potassium identified.*
Dissolution test: ***Does not comply.***
Uniformity of Dosage Units
By Weight Variation. *Complies*
Assay for Diclofenac Potassium:
Determined amount/tablet: *75.9434mg*
Stated amount/tablet: *75mg*
Percentage: *101.3%*
Limits: *90.0% to 110.0% Complies.*
Remarks:- *The sample is of **"substandard"** quality under the Drugs Act. 1976.*

The firm didn't agree to the results of CDL, Karachi and requested for retesting under Section 22(4) of the Drugs Act, 1976 and rules framed there under. On the request of the firm, the Board's portion of the sample was sent to Appellate Laboratory, NIH, Islamabad for retesting on 17-01-2019 under section 22 of the Drugs Act, 1976.

The Appellate Laboratory, NIH, Islamabad vide their test report No.03-M/2019 dated 21st February, 2019 has also declared the said sample as of substandard quality. Test results of the NIH, Islamabad are reproduced as under:

Description: *Grayish black circular, biconvex coated tablets packed in blister packing, further contained in an outer carton.*
Identification: *Diclofenac Potassium identified.*
Dissolution test:
Determined: *45.49% of the labeled amount.*
Limit: *Not less than 75%(Q) of the labeled amount.*
Does not comply with USP 39.
Assay for Diclofenac Potassium:
Determined amount/Tablet: *71.884mg*
Stated amount/Tablet: *75.0mg*

Percentage: *95.846%*
Limits: *90.0% to 110.0%*
Complies with USP 39.

Conclusion:- *The sample is of **" substandard"** quality on the basis of test performed.*

Federal Inspector of Drugs-II, DRAP, Peshawar provided that keeping in view of the test reports of CDL, Karachi and NIH, Islamabad the firm has violated Section 23(1)(a)(v) of the Drugs Act, 1976 and also provided the following names:

i. Javid Iqbal Satti, Managing Partner/Warrantor (61101-2263967-1)
ii. Mr. Kamran John, Production Incharge, (16202-4145910-1)
iii. Mr. Saeed Ayaz Khan QC Incharge (17201-3115034-5)

The Drugs Licensing Division was requested to verify/provide the names provided by the FID-II, DRAP, Peshawar and they provided the following;

M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.	Mr. Javaid Iqbal Satti **(Management)** M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.
Mrs. Shagufta Javaid Satti **(Management)** M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.	Lt. Colonel [R] Muhammad Ishaq **(Management)** M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.
Mr. Kamran John **(Production Incharge)** M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.	Mr. Saeed Ayaz Khan **(QC Incharge)** M/s Benson Pharmaceuticals Plot # 3, Man Road, National Industrial Zone, RCCI, Rawat.

Show cause notice was issued to the firm and above accused, along with the copies of CDL, Karachi & NIH, Islamabad test reports, under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-85/2018-QC dated 20-04-2020 for the following actions.

ii. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

In response to the above said show cause notice, the firm submitted their reply vide reference No. nil dated 23-04-2020 and is reproduced as under;

Reference your letter # F-NO-03-85/2018-(Qc) Dated 20-04-2020,though our internal tests on the retained samples of the said Drug still show compliance with standards of (peak pick report attached) but we certainly cannot & do not want to contest the findings of Appellate Laboratory i.e. NIH.
We are only sorry about it & beg the pardon on following grounds.

1) *The product is no more in manufacturing range because the registration of the said product had not been renewed by DRAP due to non-availability of international reference & according to our information this strength (75mg) of all other brands of Diclofenac potassium are meeting the same fate.*
2) *All formalities regarding recall of the batch/product have been completed. Copy of batch track report attached.*
3) *Benson Pharmaceutical started its production activity in year 2000. During this span of twenty years thousands & thousands of our products were sampled/ analyzed & only two batches including this one were declared substandard one based on friability & this on dissolution. This perhaps gives you an idea of our quality consciousness about pharmaceutical manufacturing.*
4) *All records of manufacturing prove that only right quantities of standard & qualitative API/ ingredients were used to manufacture this batch but UNINTENTIONAL human error on the part of our technical staff cannot be ruled out. Marketing certificates duly signed by QC, QA and Production is attached herewith.*

We therefore place ourselves at your disposal for the action that you deem right but we hope our clean manufacturing record of the past will be considered.
It is further submitted that two partners of our firm named Col® Muhammad Ishaq and Mrs. Shagufta Javid Satti are merely investor/sleeping partners and have no say in the management of any of firm's affair and they may please be treated as such.

We thank you for your guidance & patronization and are at your deposal for any further information that you may require on the subject cited above.

5) *With profound regards, we remain committed,*

Proceeding & Decision of the 296th Meeting of registration Board.

Mr. Saeed Ayaz Khan (17201-3115034-5), Quality Control In charge of M/s Benson Pharmaceutical, Islamabad appeared before the board on behalf of M/s Benson Pharmaceutical to plead the instant case. He submitted that at the time of manufacturing of the product in question all the test performed were according to the specifications.

He further added that they have shifted their premises to new place. In reply of a question from board, he replied that they have not shifted their product Registration to the new premises.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL & NIH, Islamabad decided to cancel the Registration of Keigesic-75 Tablets, Reg. No. 021577 with immediate effect.

Case No.03: OREDRED NOT TO DISPOSE OF UNDER SECTION 18 (1) (I) OF THE DRUGS ACT, 1976, EXTENSION IN PERIOD.

The Federal Inspector of Drugs-IV, DRAP, Islamabad inspected the premises of M/s Wenvovo Plot No. 31&32, Punjab Small Estate, 5C, Taxilla on 20-12-2018, and observed that the following material was placed in premises of M/s Wenvovo Plot No. 31&32, Punjab Small Industrial Estate, 5C, Taxilia in contravention of DRAP Act, 2012 Drugs Act, 1976 and rules framed there under. The stocks mentioned below was ordered not to dispose off under Schedule V (Powers of Inspectors) (1) (i) read with section (18) (1) (i) of the Drugs Act, 1976 and rules framed their under. Details are as under;

s.#	Name of Drug	Batch No &Quantity	Manufacturer	Reason of order not to dispose off
1.	**Hitazid (Ceflazidine 250mg)**	CVl14 1000Vials	M/s Wenvovo Plot No. 31&32, Punjab Small Industrial Estate, 5C, Taxilla	**Vials of above mentioned drugs were stocked (in baskets) in corridor in front of packing hall with label states " Resealing"(copy of label attached) despite the fact that no batch # was mentioned in label. QA manger informed that there is defect in sealing although she could not show the same proof.**
2.	**Lacura Inj lgm (Ceftrixone Na (lgm)**	CV095 800Vials	-do-	**-do-**
3.	**Kors inj lgm**	CV078 600 Vials	-do-	**-do-**

Competent forum was requested for grant of permission for keeping the above-mentioned material/unit cartons ordered not to dispose of for further period under section 18 (1)(i) of the Drugs Act, 1976.

M/s Wenvovo Plot No. 31&32, Punjab Small Industrial Estate, 5C, Taxilia was directed by the FID-IV, DRAP, Islamabad vide letter No.F.2-3/2011-FID-II(ISD) dated 07-01-2019 to explain their position on the reasons mentioned in the Form-1 already received to the person present at the time of the inspection.

Extension in the period of "not to dispose of stock" was conveyed vide letter No.F.13-17/2019-(QC) dated 31-01-2019 by the competent authority i.e. Chairman, Registration Board being authorized by the Registration Board for the purpose till 19th March, 2019 with request to complete the investigation for further processing.

In response to the above said letter, M/s Wenovo Plot No. 31&32, Punjab Small Industrial Estate, 5C, Taxilia submitted their reply vide letter No. nil dated 15-02-2019 and is reproduced as under:

"It is submitted that we are following strict sterile manufacturing compliance SOP#

WP/PR/SOP/211. As per procedure during aseptic/sterile manufacturing any deviation is recorded and reported i.e. DOC#WP/QA/006 & WP/QA/DEV/007. The Aluminum sealing of some of the vials were found faulty during the process and QA officer was informed and the vials were released. While vials were already rubber stoppered under class 100. Strictly followed SOP#WP/QA/SOP/036 and vials were properly resealed prior to taking these out of aseptic area. All three batches found, were under process of optical check, labeling and packing but few of them labeled "Releasing Ok" means that these were released during the manufacturing process within the sterile area before taking out those vials to non sterile area. It is ensured that we strictly follow sterile manufacturing protocols and Quality Assurance Compliance Procedure."

The FID-IV, DRAP, Islamabad has provided that keeping in view of the reply of the firm, thay have contravened the provisions of Section 23(1) (a) (iii) read with section 27 (2) (b) & (4) of Drugs Act, 1976 and provided the following names being technical and management personnels;

- Malik Arshad Mehmood (Chief Executive/Managing Director)
- Mr. Saqib Yaqoob Awan (Production Incharge)
- Mr. Muhammad Imran (Quality Control Incharge)

The Drugs Licensing Division was requested to verify/provide the names of technical persons and management for further processing of the case and they provided the following;

Mahboob sardar **(71103-2130259-3)** **Executive Director** of M/s Wenvovo Plot No. 31&32,Punjab Small Industrial Estate, 5C, Taxilia	Arshad Mehmood **(61101-6927558-3)** **Managing Director** of M/s Wenvovo Plot No. 31&32, Punjab Small Industrial Estate, 5C, Taxilia.
Muhammad Imran **(37406-5049292-3)** **Quality Control Incharge** of M/s Wenvovo Plot No. 31&32,Punjab Small Industrial Estate, 5C, Taxilia	Saqib Yaqoob Awan **(37406-1619050-7)** **Production Incharge** of M/s Wenvovo Plot No. 31&32,Punjab Small Industrial Estate, 5C, Taxilia

Show cause notice was issued to the firm and above accused under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-38/2019-QC dated 28-02-2020 for the following actions but their reply is still awaited:

i. Cancellation/Suspension of Drug Registration.
ii. Any other action the Board may deem fit.

In response to the above said showcause notice, M/s Wenovo Pharmaceuticals submitted their reply vide reference No.WP/SCN/1 dated 10 March, 2020 and is reproduced as under:

"That Ms. Mahvash Ansari FID-IV-lslamabad inspected M/s Wenovo Pharmaceuticals Taxila on 20th December, 2018, during the visit she noticed that some shippers of vials were lying in the corridor with the labels "Resealing OK". She sealed the shippers and ordered not to dispose off these till further orders. Our point of view/explanation in this regard is as under;

a. *The shipper containing Hitazid (Ceftazidime 250mg Injection) Batch No. CV114 (1000 vials) and Lacura Injection 1gram (Ceftriaxone Na 1000mg) Batch No. CV095, 800 vials were labeled as "Resealing OK". The factual position is that during production of these batches the production staff noticed some issue regarding quality of the aluminum seals of these vials. These vials were already rubber stoppered under class-100. The vials with faulty seals were segregated and the issue was resolved by resealing these vials with their respective batches while these were still in the sterile vial filling area before being taken out. To ensure quality checks, these vials were stored in separate baskets for quality assurance inspection. It is pertinent to mentioned that since the resealing problem was addressed while these vials were still in the sterile filling area /environment during production of their respective batches, no violation of GMP was made.*
b. *The shipper containing Kors Injection 1gm (Ceftriaxone Na 1gm) Batch No. CV078 around 600 vials was also in the corridor. The product had no issue of resealing or any other problem. It was there prior to be shifted to the IPQ. This product was sealed without any defect by the Honorable FID. The same is very much clear from the picture of the label on the shipper.*
c. *It is submitted that the show cause notice has been issued for violation of the provisions of Section 23 (1) (a) (iii) read with Section 27 (2) (b) & (4) of Drug Act, 1976. The Section*

23 (1) (a) (iii) of the Drug Act pertains to any misbranded drug and the Section 27 (2) (b) & (4) pertains to giving false warranty of any drug sold. Both Sections under reference in the show cause notice are not applicable to this case as neither we have misbranded any drug nor we have sold and issued any false warranty of these products. The sealed stock of the products are still at the factory premises since 20th December 2018 awaiting the decision of the competent authority.

2. *It is submitted that keeping in view the above mentioned facts the show cause notice may please be withdrawn and if required M/s Wenovo Pharmaceuticals may please be given an opportunity to be heard in person.*

Proceeding and Decision of 296th Meeting of Registration Baord.

Mr. Muhammad Imran (37406-5049292-3), Quality Control Manager of M/s Wenovo Pharmaceutical appeared before the Board on behalf of M/s Wenovo Pharmaceutical to plead the instant case. Representative of the firm reiterated the points already mentioned in their reply to the show cause notice. The Board also observed that violation established by the FID are not related to the case.

Decision of 296th Meeting of Registration Board.

The Board after thorough deliberations decided as follows;

- **To issue strict warning to the firm to strictly comply to GMP standards as per relevant provisions of law.**
- **FID / Investigation officer shall be asked to provide current status of the stock along with their manufacturing & expiry date for further necessary action.**

Case No.04: **Manufacture & Sale of Adulterated & Substandard Adyneph Injection, Reg. No. 085777, Mfg. Date May, 2018, Exp. Date April 2020, Batch no. AD-10418, Manufactured by M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore.**

The FID-VI, DRAP, Karachi visited the premises of M/s. Hashmani Medicine, Shop No. 4 Plot SB-1, Block-1, Madiha Square, Hussain FB Area, Karachi on 21-11-2019 and took the sample of Adyneph Injection, Reg. No. 085777, Mfg. Date May, 2018, Exp. Date April 2020, Batch No. AD-10418, Manufactured by M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore under Schedule-V (1)(C) of DRAP Act, 2012 read with section 18 (1)(C) of the Drugs Act, 1976. Details are as under:

Name	Adyneph Injection
Composition	Each ml contains 1mg of Adrenaline.
Registration No:	085777
Batch No:	AD-10418
Manufacturing Date:	May, 2018
Expiry Date:	April, 2020
Claimed Manufacturer:	M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, Lahore.

The sealed samples of the above said drugs was sent by the FID, DRAP, Karachi to Federal Government, Central Drugs Laboratory, Karachi for the test/analysis vide memorandum No.ARS-249-252/2019-FID-VI (K) dated 22-11-2019.

The sealed portion of sample was also sent by the FID, DRAP, Karachi to Chairman, Drug Registration Board, DRAP, Islamabad vide letter of even number dated 22-11-2019 as required under the provision of clause (b)(3) Schedule-V (Procedure for Inspector) of DRAP, Act, 2012.

M/s. Hashmani Medicines, Karachi has produced the Invoice/Bill Warranty No. 1085 dated 20th July 2018 of M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore as a proof of their purchase of above drug.

The Government Analyst, Central Drugs Laboratory, Karachi vide test reports No.NTF.KQ.566/2019 (initial) dated 02nd December 2019 and No. KQ.566/2019 (Final) dated 11th December 2019 declared the sample of the above named drug as **"Adulterated and Substandard"** under the Drugs Act, 1976, which is violation of Section 23(1) (a) (iv) and 23(l)(a)(v) of Drugs Act, 1976 and rules framed there under. Test results of CDL, Karachi are reproduced as under:

Description: *Colorless solution in ambered glass ampoule contains black particles visible to the naked eye.* ***Does not comply with BP 2019****.* ***Identification:*** *Adrenaline Acid Tartarate identified.*

pH Determined: *3.48*
Limits: *2.8 to 4.0 Complies.*
Assay for Adrenaline:
Determined amount/ml: 1.0516mg
Stated amount/ml: 1mg
Percentage: 105.2%
Limits: 90.0% to 110.0% Complies.

In the light of above test reports of Government Analyst, Central Drugs Laboratory, Karachi an explanation letters of even number dated 05th December 2019 and 12th December 2019 were accordingly issued to M/s Bajwa Pharmaceuticals Pvt. Ltd., 36KM, Off G.T Road, Lahore for explaining their position in the matter of manufacturing, selling & distributing of above mentioned Adulterated and Substandard drug with the directions to recall the above batch from the market.

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., 36KM, Off G.T Road, Lahore submitted their reply vide letter dated 24th December 2019 wherein, the firm stated that black particles not observed in retained sample, however, black particles observed in picked sample by FID that might due to following reasons and taken CAPA to avoid such issues.

i. Weak eye sight of few workers.
ii. Dimness of light in optical hood.

FID-VI, DRAP, Karachi recommended that the contents of the case may be kept on forthcoming meeting of DRB to suspend their registration and a through panel GMP inspection of firm may also be conducted for better public safety. The names of technical persons provided by the FID-VI, DRAP, Karachi are as under:

- Abdul Khaliq, Production Manager (CNIC No. 35202-2309191-7)
- Dr. Ammar Yasir Bhutta, Quality Control Manager (CNIC No. 35201-1386914-3)
- Miss Komal Kiran, Quality Assurance Manager (CNIC No. 35202-0664760-6)

The Drugs licensing Division was requested to verify/provide the names provided by the FID, DRAP, Karachi and they provided the following names as per available record:

M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**	Mr. Farhat Munawar Bajwa **(Management)** M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**
Mr. Usman Ahmad Bajwa **(Management)** M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**	Mr. Salman Ahmad Bajwa **(Management)** M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**
Ms. Raabia Munawar Bajwa **(Management)** M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**	Mrs. Nuzhat Raza **(Production Incharge)** M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**
Mr. Ahmad Raza (Quality Control Incharge) M/s. Bajwa Pharmaceutical (Pvt.) Ltd., 36-KM Off GT Road, **Lahore.**	

Show cause notice was issued to the firm and above accused along with the copies of CDL, Karachi test reports under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-61/2019-QC dated 04-05-2020 for the following actions but reply of the firm is still awaited;

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

In response to the above said show cause notice the firm submitted their reply vide reference No. BPL/MOH/20/2029 dated 11-05-2020 and is reproduced as under;

"In report, black particles were observed in Adyneph injection (batch No. AD-10418), black particles may be developed if the storage conditions are not maintained properly.
Whereas in quality control lab of Bajwa Pharmaceuticals, retained samples have complied to clarity test and no visible particulate matter was observed.
We have attached report for your kind perusal."

Proceeding & Decision of the Registration Board.

Mr. Salman Bajwa (35201-1660281-1), Director of M/s Bajwa Pharma appeared before the Board to

plead the instant case. He submitted that the retained samples of the subject cited drug were found as per specification and no black particles are visible within it. He also brought a pack of subject cited drug and further added that black particles in the subject cited drug may be due to improper storage of the drug.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL, Karachi decided as under:

- **Cancel the Registration of Adyneph injection, Reg. No. 085777 with immediate effect.**
- **The Board also constituted the following panel to conduct thorough investigation of the injectable section of M/s Bajwa Pharma and submit clear and candid recommendations regarding injectable manufacturing facility for consideration of the Registration Board;**
    - **Mr. Iftikhar Ahmad, Member Registration Board.**
    - **Director, Drug Testing laboratory, Lahore.**
    - **Mr. Ajmal Sohail Asif, DRAP, Lahore.**

Case No. 05: MANUFACTURE & SALE OF ADULTRATED & SUB-STANDARD RHINEX P SYRUP, BATCH. NO. 051 M/S OPAL LABS; (PVT), LTD. KARACHI.

The FID-VII, DRAP, Karachi visited the premises M/s Opal Laboratories (Pvt.) Ltd., located at plot No. LC-41, L.I.T.E, Landhi, Karachi wherein the sample of Rhinex P Syrup, Batch. No. 051, manufactured by M/S Opal Laboratories, (Pvt.), Ltd, Karachi was drawn along with other Drugs on 08-02-2018 under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976. Details are as under:

Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Purported to be manufactured by.
Rhinex-P Syrup	067409	051	02-2018	01-2020	M/s Opal Laboratories (Pvt.) Ltd., located at plot No. LC-41, L.I.T.E, Landhi, Karachi

The said sample was sent to the Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.DMT-07/2018- to 14/2018FID-VII (K) dated 09-02-2018 for the purpose of test /analysis.

The Federal Government Analyst, CDL, Karachi declared the aforementioned sample as of Adulterated & sub-standard quality vide test/analysis report No.KQ.87/2018, dated 11th April, 2018. Results are reproduced as under:

Description:	*Brown colored syrup, containing black particles visible to the naked eye.*
	Does not comply with manufacturer's specifications.
Identification:	*Promethazine and carbocystine identified.*
pH Determine:	*6.21*
Limits:	*5.8 – 6.3*
Assay for Carbocisteine:	
Determined amount/5ml	*98.1484mg*
Stated amount/5ml:	*100mg*
Percentage:	*98.1%*
Limits:	*90.0% to 110.0%*

REMARKS: - The sample is of "Sub-Standard" quality under the Drug Act 1976.

In Light of the CDL, Karachi test report, FID-VII, DRAP, Karachi issued an explanation letter vide reference No.DMT-07/18-FID-VII (DRAP) dated 24-04-2018 to M/s Opal Laboratories (Pvt.) Ltd., located at plot No. LC-41, L.I.T.E, Landhi, Karachi but no reply was received.

M/s Opal Laboratories (Pvt.) Ltd., located at plot No. LC-41, L.I.T.E, Landhi, Karachi was asked again to explain their position in this regard dated 25-02-2019.

M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi vide reference No. nil dated 05th March, 2019 & 14th March, 2019 submitted their reply wherein they have stated that QC tests were performed on their retention samples of Rhinex-P-Syrup, Batch No. 051and we are quite

confident that all results (Physical & Chemical) are ok, complies & meet the specifications accordingly "Brown color Syrup" containing no traces of black particles.
They have recall 2565 packs from the market and also provided the destruction summary. The destruction was conducted without intimation to/permission from DRAP. Names of the management and technical persons provided by the firm vide letter dated 05-03-2019 are as under:

i. Iqbal Ahmad **(Managing Director)**
ii. Ikram Zubairi **(G.M Plant Operations)**
iii. Rozina Babar **(Head of Quality Operations)**

The Drugs licensing Division was requested to verify/provide the names provided by the firm and they provided the following:

Mr. Ali Afzal **(Director)** M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi	Mr. Jehanzeb **(Director)** M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi
Mrs. Rozina Babar **(Q.C Incharge)** M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi	Mr. Ikram Ahsan Zubairi **(Production Incharge)** M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi

The FID, DRAP, Karachi further added that M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi is involved in manufacturing & selling of Adulterated and substandard drug which is violation of section 23 (1) (a) (iv) & 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under. Furthermore, she recommended that action may be taken as per section 42 of the Drugs Act 1976 and rules framed there under against M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi.
Show cause notice has been issued to the technical staff/management of the firm for the following action (s) - U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-28/2018-(QC) dated 24-01-2020.

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

M/s Opal Laboratories (Pvt.) Ltd., plot No. LC-41, L.I.T.E, Landhi, Karachi submitted their reply to show cause notice vide letter No. nil dated 31-01-2020 which is reproduced as under:
Refer to your letter No. 03-28/2018-(QC) dated 24-01-2020, received on 30-01-2020 regarding substandard & Adulterated drug Rhinex-P syrup, B# 051, please note that we have submitted all the required documents on dated 05-03-2019 to DRAP Area FID-VII, DRAP, Karachi and copy to QC DRAP Islamabad. Furthermore we have recalled all the remaining stock of complaint batch from Market through print media and through intimation given to all distributors.
In reference to your above mentioned letter we would like to submit as under:

- *It is submitted that we have checked retained sample of the said batch and results have found ok within the limits and meets specifications "Brown color syrup" containing no traces of black particles. We are confident that all the chemical and physical tests are alright.*
- *Details of physical and chemical analysis along with test protocol are attached for your kind reference.*

We will appreciate for meeting you for further elaboration in case of any clarification/information required.

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. Iqbal Ahmad (42201-7917477-5), Managing Director & Rozina Babar of M/s Opal Laboratory appeared before the Board on behalf of M/s Opal Laboratory, karachi to plead the instant case. They submitted before the board that retained samples were checked and were found according to the specification. No black particles were seen in the retained samples. They further added that as the retained samples were according to the specifications, therefore, they didn't apply/requested for retesting of the said product.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL, Karachi decided as under:

i. Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis, Corrective and preventive action (CAPA) by

the firm, product development data and verification of aforementioned points and Product Specific Inspection by following panel whichever is later.

- **Prof.Dr. Abdullah Dayo, Member Central Licensing Board.**
- **Mr. Affan Ali, Assistant Director, CDL, Karachi.**
- **Dr. Krishan Das, Assistant Director, DRAP, Karachi.**

Case No. 06: MANUFACTURE & SALE OF SUB-STANDARD ZAYPEP SUSPENSION, BATCH NO. 18023 BY M/S ZAYNOON PHARMACEUTICALS (PVT.) LTD, PESHAWAR.

The FID-III, DRAP, Islamabad visited the premises M/s New Al-Shifa Medicose, 1st Floor Al-Shifa Hotel, New Murree on 25-05-2018 wherein the sample of Zaypep Suspension, Batch No. 18023, manufactured by M/s Zaynoon Pharmaceuticals (Pvt.) Ltd, Peshawar was drawn under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976 for the purpose of test/analysis. Details are as under;

Name of Product	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Purported to be manufactured by.
Zaypep Susp. 120ml	017633	18023	02-2018	01-2020	M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar

The sealed sample of said drug was sent to the Federal Government Analyst, Central Drugs Laboratory, Karachi for test & analysis on 28-05-2018 and other sealed portions were dispatched as per DRAP Act, 2012 read with the Drugs Act, 1976.

M/s New Al-Shifa Medicose, 1st Floor Al-Shifa Hotel, New Murree has submitted the bill/invoice with warranty No. 223924 dated 14-05-2018 in favor of the said drug issued to them by M/s FM distributor, B-364/A, Collage Road, Rawalpindi.

M/s FM distributor, B-364/A, Collage Road, Rawalpindi was directed by the FID-III, DRAP, Islamabad vide letter dated 28-05-2018 to confirm the said warranty and to send the sealed portion of the sample from whom they have purchased the same and to provide subsequent bill/invoice with warranty along with original receipt of sending sample.

M/s FM distributor, B-364/A, Collage Road, Rawalpindi has confirmed the said bill/invoice with warranty issued by them to M/s New Al-Shifa Medicose, 1st Floor Al-Shifa Hotel, New Murree and further provided the subsequent bill/invoice with warranty No. 772 dated 28-04-2018 of M/s Absar traders in favor of the said drug.

M/s Absar traders, Shop No. 11, 1st floor, Al Marba Market Namak Mandi, Peshawar was directed by the FID-III, DRAP, Islamabad vide letter dated 11-06-2018 to confirm the warranty and provision of subsequent warranty of the manufacturer but M/s Absar traders, Peshawar vide letter No. 19-ATP-002 dated 01-07-2019 after lapes of period more than seven months confirmed their bill invoice with warranty and receipt of warrantor portion but subsequent bill invoice with warranty of M/s Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar has not been provided.

The Federal Government Analyst, CDL, Karachi declared the aforementioned sample as of sub-standard quality vide test/analysis report No.IP.138/2018, dated 03-08-2018. Results of the report are reproduced as under:

Description:	*Off white suspension in ambered glass bottle.*
Identification:	*Famotidine identified.*
pH Determined:	*5.60*
Limits:	*6.5 to 7.5* ***Does not comply.***
Assay for Famotidine:	
Determined amount/5ml:	*6.5745mg*
Stated amount/5ml:	*10mg*
Percentage:	*65.7%*
Limits:	*90.0% to 110.0%* ***Does not comply.***

Remarks:- *The sample is of* ***" substandard"*** *quality under the Drugs Act. 1976.*

The FID-III, DRAP, Islamabad issued an explanation letter dated 15-08-2019 to M/s Zaynoon Pharmaceuticals with direction to stop the sale, recall the said drug and explain their position on manufacturing and selling of the said substandard drug.

In compliance to the above said letter, the firm replied vide letter No. ZPPl/QC/010 dated 27-08-2018 and Ref. No. ZPPL/QC/18/023 dated 11-09-2018 wherein the firm only challenged the said test report under section 22 (4) of the Drugs Act, 1976 whereas no information regarding recall and stoppage sale of the said drug was provided.

On the request of the firm, the Board's portion of the said sample was received in the Appellate Laboratory, NIH, Islamabad vide No.F.03-67/2018-QC dated 23-11-2018 as required under section 22 (5) of the Drugs Act, 1976.

Appellate laboratory, NIH, Islamabad vide their test report No.30-M/2018 dated 03-01-2019 declared the said sample as of substandard quality. Results of the test report of NIH report are reproduced as under:

Description:	*Off white suspension contained in amber colored labeled glass bottles further packed in an outer carton.*			
Identification:	*Famotidine identified.*			
Volume:	***Determined:*** *120ml*		***Limits:*** *120ml*	
	Complies with volume stated on the label.			
pH	***Determined:*** *5.40*		***Limits:*** *6.5-7.5*	
	Does not comply with USP 39.			
Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Famotidine	*10mg/5ml*	*7.634mg/5ml*	*90-110%*	*76.343%*
	In the opinion of the undersigned the sample is of substandard quality as defined in the Drugs Act, 1976 for the reason(s) given below:			
pH	***Determined:*** *5.40*		***Limits:*** *6.5-7.5*	
	Does not comply with USP 39.			
Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Famotidine	*10mg/5ml*	*7.634mg/5ml*	*90-110%*	*76.343%*

The FID-III, DRAP, Islamabad submitted that in view of the test report of CDL, Karachi and Appellate Laboratory, NIH, Islamabad firm has violated section 23 (1)(a)(v) of the Drugs Act, 1976. The firm, M/s Absar Traders Peshawar and M/s FM Distributors, B-364/A, College Road Rawalpindi were once again directed to stop the sale, recall the said drug and explain their position in manufacturing and selling of the said substandard drug and to furnish required information within 07 days. The reply of the firm and M/s Absar Traders, Peshawar has been received but M/s FM Distributor, B-364/A, College Road, Rawalpindi Distributor, B-364/A, College Road, Rawalpindi has not replied yet so for.

M/s Absar Traders, Peshawar replied that they confirmed their bill invoice with warranty issued to M/s FM Distributor, Rawalpindi in favor of said drug and also acknowledged receipt of sample of warrantor portion but did not provide the subsequent bill invoice with warranty of the manufacturer and proof of receipt of warrantor portion to the manufacturer. Hence M/s Absar Traders, Peshawar contravened section 32 (3) (b) (i), schedule-III (3) (4) read with 27 (3) (4) (schedule VI) of DRAP Act, 2012 and M/s FM Distributor, B-364/A, College Road, Rawalpindi contravened section 32 (3) (b) (i), schedule-III (3) (4) read with 27 (3) (4) (schedule VI) of DRAP Act, 2012.

M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar has replied that this product has been recalled w.e.f 29-08-2018 after receiving CDL, Karachi report and assured the stoppage of sale and use of the said drug; Cutting of News Paper/ circular and bill invoice with warranty issued to M/s Absar Traders, Peshawar. They further furnished the authority letters issued to M/s Absar Traders and M/s FM Distributors, Rawalpindi to sale their said drug and also confirmed the receipt of warrantor portion. Hence, the firm contravened Section 23(1)(a)(v) of Drugs Act, 1976 and DRAP Act, 2012. No evidence about recalled quantity has been provided from firm or both distributors. Following actions are proposed against the said firm/ distributors.

i. Cancellation / suspension of DML/ cancellation of registration of said drug.
ii. Recommendation of Cancellation/ suspension of Whole Sale Licenses of both distributors to the concerned authority.

iii. Prosecution in the Drug Court against the persons mentioned below:

S.#.	Name.	CNIC #	Designation
1.	Mr. Muhammad Nadeem Gul.	17301-1301410-5	Chief Executive of the firm.
2.	Mr. Sadaqat Ali Khan.	31202-5101935-7	Production In-charge.
3.	Mr. Shaukat Ayaz.	15402-7372422-3	QC In-charge.
4.	Mr. Muhammad Umer Malik.	37405-7614227-3	Proprietors of FM distributors
5.	Mr. Anwar Saeed Khan.	11201-3406586-3	Qualified person.
6.	Mr. Islam Gul		Proprietors of Absar Traders.
7.	Mr. Kaleemullah.	-	-do-
8.	Mr. Muhammad Javeed.	-	Qualified person.

The Drugs Licensing Division, DRAP, Islamabad was requested to verify/provide the names provided by the FID-III, DRAP, Islamabad and they provided the following:

M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar	Muhammad Nadeem Gul **(Director/Management)** M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar
Khalid Naeem **(Director/Management)** M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar	Sadaqat Ali Khan **(Production Incharge)** M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar
Shaukat Ayaz **(QC Incharge)** M/s. Zaynoon Pharmaceuticals (Pvt.) limited, 27-28-B, Industrial Estate, Hayatabad, Peshawar	

Show cause notice was issued to the firm and above accused along with the copies of CDL, Karachi and NIH, Islamabad test reports under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-67/2018-QC dated 03-02-2020 for the following actions;

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

M/s. Zaynoon Pharmaceuticals (Pvt.) limited, Peshawar vide reference No. ZPPL/QC/020/004 dated 13-02-2020 submitted their reply in response to the above said show cause notice and is reproduced as under:

i. We have provided that finished product specification to CDL, Karachi as well as NIH, Islamabad with the request to check the product as per method as we develop the product and esteemed laboratories did not adopt the method so we are still aggrieved.

ii. As per your instructions, we have recall all the stock from the market of the said batch as advised and we are abide by the Drugs Act, 1976 and DRAP Act, 2012 and rules framed there under.

iii. It is also requested to give us an opportunity of personal hearing for the explanation of our grievances before Registration Board regarding the case.

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. Shaukat Ayaz (15402-7372422-3), Quality Control Manager M/s Zaynoon Pharmaceuticals, Peshawar appeared before the Board on behalf of M/s Zaynoon Pharmaceuticals, Peshawar to plead the instant case. He reiterated the points already mentioned in their reply to the show cause notice as recorded above.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL, Karachi decided as **under:**

i. **Applicants shall revise their formulation as per innovator drug product which is available as dry powder for suspension in the strength of 40 mg/ 5 ml, if manufacturing facility is approved by CLB.**
ii. **The firm shall submit new application with complete fee to the relevant registration section for the change of their formulation as per innovator's product which is available as dry powder for suspension in the strength of 40 mg/ 5 ml.**
iii. **The product shall remain suspended till the approval of the revised formulation as per innovator's product.**

Case No. 07: MANUFACTURE & SALE OF SUB-STANDARD ALFASUN 1MCG CAPSULES BATCH NO.C325 BY M/S HISUN PHARMACEUTICAL INDUSTRIES, GADOON.

The Federal Inspector of Drugs, DRAP, Peshawar visited the premises of M/s Hisun Pharmaceutical Industries, Gadoon on 12-04-2018 wherein the sample of Alfasun 1mcg Capsules, Batch No.C325 manufactured by M/s Hisun Pharmaceutical Industries, Gadoon was drawn under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976 for the purpose of test/analysis. Details are as under;

Name	Alfasun 1mcg Capsules
Composition	Each capsule contain 1mcg Alfacalcidol.
Registration No:	064083
Batch No:	C325
Manufacturing Date:	04-17
Expiry Date:	03-19
Claimed Manufacturer:	M/s Hisun Pharmaceuticals Industries, **Gadoon.**

The said sample was sent to the Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.F.10-34/2018-Hisun-DRAP (P) dated 13-04-2018.

The Federal Government Analyst, CDL, Karachi declared the sample as of sub-standard quality vide test/analysis report No.IP.109/2018, dated 04th July, 2018. Results of the CDL's test report are reproduced as under:

Description: *Red and black colored capsules, containing off white powder.*
Identification: *Alfacalcidol identified.*
Assay for Alfacalcidol:
Determined amount/Capsule: *0.4034mcg*
Stated amount/Capsule: *1mcg*
Percentage: *40.3%*
Limits: *90.0% to 110.0%* ***Does not comply.***
Remarks:- *The sample is of* ***" substandard"*** *quality under the Drugs Act. 1976.*

The firm didn't agree with the results of the aforementioned report of CDL, Karachi and challenged the report under Section 22(4) of the Drugs Act, 1976 for retesting from Appellate Laboratory, NIH, Islamabad.

Appellate Laboratory, NIH, Islamabad vide their test report No.021-M/2018 dated 21-02-2019 has also declared the said sample as of substandard quality. Results of the NIH, Islamabad test report are reproduced as under:

Description: *White powder contained in black and red capsule shells packed in blister packing further contained in an outer carton.*
Identification: *Alfacalcidol identified.*
Weigh variation: ***Does not comply with BP-2017.***
Disintegration Time: ***Determined:*** *22 minutes* ***Limits:*** *NMT 30 minutes*
Complies with BP-2017.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Alfacalcidol	*1mcg/Capsule.*	*0.3319mcg/Capsule.*	*Nil*	*33.19%*

In the opinion of the undersigned the sample is of substandard quality as defined in the Drugs Act, 1976 for the reason(s) given below:

Weigh variation:	***Does not comply with BP-2017.***			
Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Alfacalcidol	*1mcg/Capsule.*	*0.3319mcg/Capsule.*	*Nil*	*33.19%*

Federal Inspector of Drugs, DRAP, Peshawar provided the following names:

- Mr. Rana Muhammad Nawaz-**Managing Director.**
- Mr. Sardar Ahmad – **Production Incharge** (at the time of production of Alfasun 1mcg Capsule).
- Mr. Abdullah Abu Bakar – **Production Incharge** (Current).
- Mr. Sajjad Ali Khan – **(Quality Control Manager)**

The Drugs Licensing Division was requested to verify/provide the names provided by the FID, DRAP, Peshawar and they provided the following;

M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**	Rana Muhammad Nawaz **(Management)** M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**
Muhammad Barhan-ud-din **(Management)** M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**	Shafiq Ur Rehman **(Management)** M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**
Sardar Ahmad **(Production Incharge)** M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**	Sajjad Ali Khhan **(Quality control Incharge)** M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate, **Gadoon.**

Show cause notice was issued to the firm and above accused, along with the copies of CDL, Karachi & NIH, Islamabad test reports, under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-67/2018-QC dated 03-02-2020.

In response to the above said show cause notice, the firm submitted their reply vide reference No. Alfasun01/2020 dated 20th February, 2020 and is reproduced as under:

"Reference to your letter No.F.No.03-61/2018-(QC) dated 3rd February 2020 regarding our product ALFASUN 1mcg Capsule having manufacturing date April 2017 and Expiry date March 2019 that is declared as Substandard by CDL Karachi and Appellate Laboratory NIH Islamabad, we came to the following conclusion by identifying the root cause.

- *The quantity of active ingredient (AlfacaIcidol) in Batch is very minute hence extremely difficult to mix it with other excipient, further we do not have the proper mixer for such sensitive mixing and we do declare that we like most of other pharmaceutical industries manually mix the batch without proper mixer.*
- *The second reason that we have concluded is that even after proper mixing but in slight weight variation of capsules the active ingredient quantity varies to a large extent.*

We also want to inform you that particular batch has already expired as on March 2019 and same was recalled from market and the stock is sealed by Area FID, DRAP Peshawar Mr. Atiq- ul-Bari in our Finish Goods Store.

Regarding the show cause notice we the management of this firm has decided to surrender and deregister Alfasun 1mcg having registration No.064083.

We also want to request the Area FID DRAP Peshawar for destruction of the sealed stock. Aforesaid in view a favorable action is requested please".

The FID, DRAP, Peshawar also informed that stock of 05 Cartons x 250 Packs x 20 Capsules were not to dispose of on form 1 on 06-08-18. On 27-09-18 stock of 278 packs x 20 capsules and on 17-01-19 stock of 250 packs x 20 capsules were not to dispose of on form-1and also seek directions from the Registration Board for the fate of the said stock.

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. M. Nawaz (34601-9588618-1), Owner of M/s Hisun Pharmaceutical Industries, Gadoon appeared before the Board on behalf of M/s Hisun Pharmaceutical Industries to plead the instant case. The

owner of the firm submitted before the Board that they want to discontinue their product as the concentration of the active is very low & it is very difficult to mix it properly.

Decision of 296th meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the test reports of CDL, Karachi, statement of the firm decided as under:

- **To cancel the Registration of Alfasun 1mcg Capsules, Reg. No. 064083 with immediate effect.**
- **Destruction of the stock 05 Cartons x 250 Packs x 20 Capsules, 278 packs x 20 capsules & 250 packs x 20 capsules in the presence of Area FID and certificate of destruction dully signed by the Owner/representative of the firm and Area FID.**

Case No. 08: **Manufacture & Sale of Sub-Standard Drug Pearle White Cotton Bandage B.P Type-II, Batch No.PWB-0901, Reg. No. 042254 manufactured by M/s Sultan Cotton & Bandage, Mirpurkhas, Sindh.**

The FD-VI, DRAP, Karachi visited the premises of M/s. Al Shifa Medical Store, 1499/3, Opposite Bank- Al Habib, Main Road, Siddiq abad, FB Area, Karachi on 12-02-2019 in light of NTF and took the sample of Pearle White Cotton Bandage B.P Type-II, Batch No.PWB-0901, Reg. No. 042254 manufactured by M/s Sultan Cotton & Bandage, Mirpurkhas, Sindh for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Mfg. By
Pearle White Cotton Bandage BP Type-II R#042254	**PWB- 0901**	Sep 2018	Use within 3 years	M/s. Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road, Mirpurkhas

A sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for test/analysis vide memorandum No. ARS-07/2019- FID-VI (K) dated 13-02-2019.

The sealed portion of the said sample was also sent to Chairman, Drug Registration Board, DRAP, Islamabad vide letter of even number dated 13-02-2019 as required under the provision of clause (b)(3) Schedule-V (Procedure for Inspector) of DRAP, Act, 2012.

The sealed sample (manufacturer portion) of under reference drug was sent to M/s. Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road, Mirpurkhas vide letter of even number dated 25-02-2019 as required under the provision of clause(c) (3) Schedule-V (Procedure for Inspector) of DRAP Act, 2012.

M/s. Al Shifa Medical Store, 1499/3, Opposite Bank Al Habib, Main Raod, Siddiqabad, FB Area, Karachi has produced invoice/bill warranty No. 0001 dated 08-02-2019 of M/s. Hashmani Medicine, Shop No. 4, Plot sb#l, Block-1, Sharifabad, Near Usman Hospital, FB Area, Karachi as a proof of their purchase of above said drug.

M/s. Hashmani Medicine, Shop No. 4, Plot sb#l, Block-1, Sharifabad, Near Usman Hospital, FB Area, Karachi was directed by FID, DRAP Karachi to produce the subsequent invoice/bill warranty of above said drug under Section 23(1)(i) of Drug Act, 1976 vide letter of even number dated 06th March 2019. M/s. Hashmani Medicine, Shop No. 4, Plot sb#l, Block-1, Sharifabad, Near Usman Hospital, FB Area, Karachi has produced subsequent invoice/bill warranty No. F.0105 dated 16-11-2018 of M/s. Medicine House, Shop No. 1&2, Plot No. 50, Block-3, Near Edhi Centre, FB Area, Karachi. Subsequently, M/s. Medicine House, Shop No. 1&2, Plot No. 50, Block-3, Near Edhi Centre, FB Area, Karachi vide letter dated 14th March has produced invoice No. 1102 dated 06-11-2018 of M/s. Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road, Mirpurkhas of purchase of above said drug.

The Government Analyst, Central Drugs Laboratory, Karachi vide test report No.R.KQ.166/2019 dated 28th February 2019 declared the sample as of **"Substandard"** quality under the Drugs Act, 1976, which is violation of Section 23(1) (a) (v) of Drugs Act, 1976 and rules framed there under. Results of the test are reproduced as under:

> ***"Description:*** *Open wove bandage consist of fabric of plain wave. It is practically odorless, not reasonably free from weaving defects and contains not more than traces of leaf residue seed coat and other impurities. It is not in one continuous length. The edges are not*

cut evenly parallel to the warp threads and are not reasonably free from loose threads.
Does not comply with B.P 1988.

Fiber Identification test: *Complies.*

Treads per 10cm:	*Determined:*	*Limits.*
Warp:	*127.56*	*135 to 163 Does not comply.*
Weft:	*69.29*	*84 to 95 Does not comply.*
Weigh per unit area:	*41.09gm/m^2*	*Not less than 33gm/m^2 Complies.*

Remarks: *The sample is of* ***sub-standard*** *quality under the drugs Act. 1976.*

On the request of the firm, sample was sent for retesting from Appellate laboratory, NIH, Islamabad dated 14-06-2019 under section 22(4) of the Drugs Act, 1976. The Appellate laboratory, NIH, Islamabad vide their test report No. 012-M/2019 dated 09-07-2019 has declared the sample as of substandard quality. Results of the test are reproduced as under:

Description: *Off white cloth of plain weaves, bleached not to a good white. The bandage is not in one continuous length, containing joins and have weaving defects. The edges are no evenly cut parallel with the wrap threads and have loose threads on the either sides of the bandage. The bandage is packed in khaki paper and further packed in printed khaki envelop. (Does not comply with B.P 1988 which states that "" Cotton cloth of plain weaves, bleached to a good white, in one continuous length containing no joins and reasonably free from weaving defects, leaf and shells. The edges are evenly cut, parallel with the wrap threads, and are reasonably free from loose threads").*

Identification:	*Cotton fibers identified.*	
Size:	***Determined:***	*5cm x 3.0m*
	Limit:	*5cm x 3.0m.*
	Complies with size stated on the label.	
Threads per stated length:		
Warp per 10cm	***Determined:***	*Average 115 threads/10cm*
	Limit:	*135-163 threads/10cm*
Weft per 10cm	***Determined:***	*Average 75 threads/10cm*
	Limit:	*84-96threads/10cm*
	Does not comply with BP 1988.	
Weight per unit area:		
	Determined:	*Average32.51gm/m^2*
	Limit:	*Not less than 33.0gm/m^2*
Water soluble and ether soluble substances:		
	Determined:	*1.45%*
	Limit:	*Not more than 1.5%*
	Complies with BP-1988.	

The FID-VI, DRAP, Karachi recommended that as the firm has violated section 23(1)(a)(v) of the Drugs Act, 1976 and rules framed there under therefore, the registration of their under reference product may kindly be suspended/cancelled for a certain period being a non safer drug and all other drugs being manufactured at their premises may kindly be reviewed after detailed GMP inspection by the panel. The names of responsible persons provided by the FID, DRAP, Karachi are as under:

i. Tahir Rasheed, Director (CNIC No. 44103-0293309-6).
ii. Abdul Sattar, General Manager (CNIC No. 44103-0303363-3).
iii. Basharat Ali, Quality Control Manager (CNIC No. 44103-9097095-5).
iv. Nusrat Sultan, Production Manager (CNIC No. 42201-1618043-3).

The Drugs licensing Division was requested to verify/provide the names provided by the FID, DRAP, Karachi and the provided the following names as per available record:

M/s Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road, **Mirpurkhas**.	Muhammad Akram Sultan **(Director)** M/s Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road, **Mirpurkhs.**

Tahira Akram Sultan **(Director)** M/s Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road **Mirpurkhas.**	Nusrat Sultan **(Production Incharge)** M/s Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road **Mirpurkhas.**
Mukhtiar Ahmad **(Q.C. Incharge)** M/s Sultan Cotton & Bandages, 145-146, Sindh Small Industrial Estate, Mirwah Road **Mirpurkhas.**	

Show cause notice was issued to the firm and above accused along with the copies of CDL, Karachi and NIH, Islamabad test reports under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-15/2019-QC dated 19-02-2020 for the following actions:

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

In response to the above said show cause notice, the firm submitted their reply vide letter No. nil dated 22-02-2020 and is reproduced as under:

"With reference to your letter No. 03-15/2019-QC received by us on 22/02/2020 we, Directors, Dr. Muhammad Akram Sultan & Tahira Akram Sultan, QC Incharge Mr. Mukhtiar Ahmed, Production Incharge Miss Nusrat Sultan, on behalf of Sultan Cotton & Bandages, Mirpurkhas hereby deeply apologize here for our mistake of contravening the provisions of 23(1)(a)(v) of the Drug Act, 1976 and the rules made their under as well as the conditions of Registrations.

We have been in the Industry for almost fifteen years and have always opt to manufacture quality product for our consumers. Sir, we are the only registered Cotton & Bandage Factory in the deprived area of interior Sindh, facing power failures, destroyed infrastructure ,almost no sweet water facility and with shortage of technical staff we are still running our firm as it is a source of earning for 30 + workers who are living in different villages nearby our factory.

Sir, we were buying bandage cloth from Tandoadam and we make sure to check every bundle of cloth (normally 100 yard) by applying all testing protocols. Sir, we have come to a conclusion that we may have received mix bundle with some yards of short pic threads by the suppliers which has led to substandard quality, we would like to bring into your kind knowledge that since February 2019 we are buying bleached cloth from Punjab which is made up of fresh yarn and is better than that of Tandoadam cloth.

We accept that the mistake has been made on our part as some short pic cloth has been over looked and consumed. Our firm's almost 80% expenses are covered from our Bandages sale. We would not be able to bear any losses because of the outcome of adverse decision against us. We are still not established in this region as Sindh is a huge market for unregistered Bandages Cotton wool & Crepe Bandage and Hyderabad is the Hub of producing illegal unregistered Bandage I Crepe Bandage Gauze etc which is only few kilometers away from Mirpurkhas.

Sir, we have already collected all stock of the mentioned batch when F.I.D Mr. Abdul Rasool Sheikh first intimated us to recall from the market through his letter No.F.ARS-07/2019-FID-VI (K), at last we request your honor & the Drug registration Board to accept our apology ,we assure you that we will strictly follow rules set under BP-1988, in testing and manufacturing of Cotton Bandage BP type -II.

Hoping for the positive decision and support of the competent authority"

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. Imran Bari (4503-0800603-9), Manager of M/s Sultan Cotton & Bandage, Sindh appeared before the Board on behalf of M/s Sultan Cotton & Bandage to plead the instant case. He reiterated the points already recorded above. In reply to a question from a board member, he submitted that have submitted their application for grant of License in the Medical Devices & Medicated Cosmetic Division.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case decided to issue strict warning to the firm to strictly comply to GMP standards as per relevant provisions of law.

Case No.09: Manufacture & Sale of Sub-Standard Drug Nim D3 Injection Batch No.P560 Reg. No. 090190 manufactured by M/s Nimrall Laboratories, Islamabad.

The FID-III, DRAP, Islamabad visited the premises of M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Islamabad on 05-12-2018 and drawn the sample of Nim D3 Injection, Batch No. P560, Reg. No. 090190 manufactured by M/s Nimrall Laboratories, Islamabad under Schedule-V (1)(C) of DRAP Act, 2012 read with section 18 (1)(C) of the Drugs Act, 1976. Details are as under:

Name of the Product	Manufactured by	Registration #	Batch #	Mfg date	Exp Date
Nim D3 5mg/ml Injection	M/s Nimrall Laboratories, Plot No. 24. Street No. SS-3, Rawat Industrial Estate, Islamabad	090190	P560	10-2018	10-2020

A sealed sample of the said drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for test & analysis on 06-12-2018 and other sealed samples were dispatched as per DRAP Act, 2012 read with Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the above said sample as of sub-standard quality vide test/analysis report No.IP.302/2018, dated 09-01-2019. Results of the test report of CDL, Karachi are reproduced as under:

Description: *Clear colorless oily solution in ambered glass ampoule.*
Identification: *Cholecalciferol identified.*
Bacterial Sterility Test: *Complies.*
Assay for Cholecalciferol:
Determined amount/ml: *3.4707mg*
Stated amount/ml: *5mg*
Percentage: *69.4%*
Limits: *90.0% to 120.0%* ***(Does not Comply.)***
Remarks: *The sample is of* ***sub-standard*** *quality under the drugs Act. 1976.*

The FID-III, DRAP, Islamabad stated that in view of the test report of Federal Government Analyst, Central Drugs Laboratory, Karachi the firm has violated Section 23(l)(a)(v) of Drugs Act, 1976. The firm was directed to stop the sale, recall the said drug and explain their position on manufacturing and selling the said "Substandard'' drugs and to furnish following information within 07 days.

- Name of Chief Executive/Director along with attested copies of CNIC.
- Name of Production In-charge along with attested copies of CNIC.
- Name of Quality Control In-charge along with attested copies of CNIC.
- To provide batch history, production and quality control records along with the sale record.

In compliance to the above said letter the firm replied vide letter No. nil dated 22-01-2019 wherein they have challenged the said test report under section 22 (4) & (5) of Drug Act, 1976 whereas did not inform about recall & to stop the sale of the said drug and other record/ information asked for in above para.

On the request of the firm, sample was sent for retesting from Appellate laboratory, NIH, Islamabad dated 18-03-2019 under section 22(4) of the Drugs Act, 1976. The Appellate laboratory, NIH, Islamabad vide their test report No. 05-M/2019 dated 15-05-2019 has declared the sample as of substandard quality. Results of the test report of Appellate Laboratory NIH, Islamabad are reproduced as under:

Description: *Clear colorless liquid contained in amber colored labeled glass ampoules, place in a transparent plastic rack further packed in an outer carton.*
Identification: *Cholecalciferol identified.*
Sterility test: *Sterile.*
Assay of Cholecalciferol:

Stated: *5mg/ml ampoule.*
Found: *3.117mg/1 ml ampoule.*
Limit: *90-120%*
Percentage: *62.351%*

Does not comply with alternate specification (Scotmann Pharmaceuticals 5-D Industrial Area I-10/3 Islamabad.)

Remarks: ***Reference of specifications (B.P Specifications) is mentioned on the label however it could not be followed due to some technical constraints, moreover manufactured fail to supply his own specifications therefore alternative specifications Scotmann Pharmaceuticals 5-D Industrial Area I-10/3 Islamabad) followed for test and analysis of Nim D3 Injection (Cholecalciferol).***

Conclusion: *The sample is of substandard quality on the basis of tests performed.*

The FID-III, DRAP, Islamabad further stated that in view of the test report of Federal Government Analyst & the Appellate Labs, Islamabad, the firm have violated Section 23(l)(a)(v) of Drugs Act, 1976. The firm was once again directed to stop the sale, recall the said drug and to explain their position on manufacturing and selling the said "Substandard" drug and to furnish desired information within 07 days.

M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Islamabad has replied that this product has been recalled w.e.f 28-01-2019 after receiving report and assured the stoppage of sale and use of the said drug. The recalled stock has been received in warehouse on 30-01-2019.

The FID-III, DRAP, Islamabad further submitted that as the firm has contravened Section 23(l) (a) (v) of Drugs Act, 1976 and DRAP Act, 2012. Following actions are proposed against the said firm:

- Cancellation / suspension of DML/ cancellation of registration of said drug.
- Prosecution in the Drug Court against the persons mentioned below:

S.#	Name.	CNIC #	Designation
1.	Mr. Shahzad Saeed.	37405-5119440-7	Chief Executive of the
2.	Syed Musarat Ali.	32102-4345781-1	Production In-charge.
3.	Mr. Miraj Khalid.	Missing	QC In-charge.

The Drugs licensing Division was requested to verify/provide the names provided by the FID, DRAP, Karachi and provided the following names as per available record:

M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Islamabad	Shahzad Saeed (37405-5119440-7) Chief Executive of M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate,Islamabad
Syed Musarat Ali (32102-4345781-1) Production In-charge M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate,Islamabad	Miraj Khalid (16102-4228315-7) M/s Nimrall Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate,Islamabad

Show cause notice was issued to the firm and above accused along with the copies of CDL, Karachi and NIH, Islamabad test reports under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-02/2019-QC dated 19-02-2020 for the following actions;

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

The firm submitted their reply to the above said show cause notice vide reference no. nil dated 27-02-2020 and is reproduced as under;

" With reference to your letter No.3-02/2019-QC dated 24-02-2020. In this regard, according to CDTL Karachi Test report No.IP.302/2018 dated 19-01-2019, our product (Nim D3 Injection) does not comply with USP 41 Specifications. The Appellate laboratory, NIH, Islamabad vide their test report No.05-M/2019 dated 15-05-2019 has declared the sample as of substandard quality by using Scotmann Pharmaceutical Specifications as mentioned in the report. But we apply B.P Specifications

as mentioned in the Unit carton and registration letter. We reuest to be heard in person and hear our point of view and position.
We have already recalled the said batch No.(P560) of Nim D3 Injection as per instructions of area FID"

Proceeding & Decision of the 296th Meeting of Registration Board.

Mr. Syed Musarat Ali (32102-4345781-1), Production manager of M/s Nimrall Laboratories, Islamabad appeared before the Board on behalf of M/s Nimrall Laboratories to plead the instant case. He reiterated the points already recorded above. He further submitted that they have recalled most of the stock of the said batch and up to 79% of the stock is in their warehouse and is almost expired.

The Board observed that CDL, Karachi applied USP protocols and NIH, Islamabad applied Scottman protocols while the product is registered with BP specifications.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case decided as follows;

- **The firm shall apply for correction of product specification as per innovator's product to the PE&R Division of DRAP.**
- **Meanwhile there shall be no production of the said drug till approval of change of specification as per innovator's product.**

Case No. 10: CASE REFERRED BY PQCB, PUNJAB REGARDING APOCLOX 500MG INJECTION MANUFACTURED BY M/S PDH LABORATORIES.

Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/ISU-4-DTL-M-209/19 dated 17-07-2019 has informed that Government Analyst Drug Testing Laboratory, Multan vide letter No. 841 dated 25-05-2019 requested guidance regarding test/analysis of Inj Apoclox 500 mg (Ampicillin+Cloxacillin), **Batch** #1901368 which is not present in USP or BP and the MS of respective manufacturer contains three chemicals (Acetic anhydride (currently banned in Pakistan), 1,4 Dioxane, Recrystallized imidazole) which are currently not, present in DTL Multan.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject issue was considered by the Provincial Quality Control Board under section 11 of the Drugs Act, 1976 in its **208th meeting held on 27-06-2019.** The Board after detailed discussion and deliberation decided to issue a show cause/ personal hearing notice to M/s PDH Laboratories to appear before the board in next meeting of PQCB along with their method of testing and approved source of purchase of chemicals used for testing.

Personal Hearing notice dated 8th July, 2019 was served to the firm.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

The above mentioned issue was discussed in 209th meeting of Provincial Quality Control Board held on 17-07-2019. The Board after detailed discussion and deliberation decided to allow the Drug Testing Laboratory Multan to file the case of Inj. Apoclox 500 mg (Ampicillin+Cloxacillin), Batch #1901368 due to use of Acetic anhydride for analysis as this chemical is currently banned in Pakistan and *Board has also recommended DRAP for cancellation of registration of the above-mentioned product due to use of banned chemical for its analysis. The Board further directed the M/S PDH Laboratories to stop manufacturing of this product till the validated method approved by the DRAP.*

Decision of 293rd meeting of Registration Board.

Registration Board after detailed discussion decided to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the Provincial Quality Control Board (PQCB), Punjab due to use of banned chemical for analysis of the product in question."

Show cause notice as per decision of the Registration Board was issued to the quarter concerned vide Letter No.F.03-65/2019-QC (293rd RB) dated 21-04-2020.

In response to the above said show cause notice M/s PDH Laboratories (Pvt.) Ltd., Lahore submitted their reply vide reference No.PDHL/DRAP/20/0464 dated 28th April, 2020 and is reproduced as under;

In reference to the letter # F.No.03-65/2019-QC (293rd) received on 25-04-2020 regarding the use of

Acetic Anhydride in the Method of Analysis of Apoclox injection-500 mg Batch # 1901368.
Matter of the fact is that, the said chemical was never used in Method of Analysis of Apoclox- injection 500mg, since the time Acetic Anhydride had been banned by the Government of Pakistan. The aforesaid chemical was just in the list of reagents but never used for the purpose of analysis since 2006. Of course, this reagent needed to be deleted from the list but it just went overlooked due to human error, from the list of reagents mentioned in the Method of Analysis that was sent to Multan DTL vide letter No.841 dated 25-05-2019 regarding test/ analysis of Apoclox injection 500mg (Ampicillin + Cloxacillin) for batch# 1901368.
Multan DTL referred the matter to PQCB which issued the notice to the firm vide letter No. PQCB/VAC-341/19 regarding the use of the Acetic Anhydride in Method of Analysis of Apoclox Injection 500mg. In that meeting we had a clear stance that the aforesaid chemical was never used in the process of analysis and it was just a human error that the chemical was still present in the list of reagents despite of the fact that it is never been used. It was mistakenly concluded that the company is using a ban chemical (Acetic Anhydride) for the test /Analysis of Apoclox injection 500mg.
Now we have updated our method analysis including the list of reagents used. We have attached the copy of corrected (with the deletion of acetic anhydride from the list of reagents) method of analysis that is actually used for the testing and analysis of Apoclox injection 500mg batch No. 1901368, for your reference.
In reference to the letter from PQCB (No.PQCB/ISU-4-DTL-M-RP/19) we have already submitted an application for the approval of the new Method of Analysis of Apoclox injection 500mg along with its validation, to the DRAP. Also, in response to that application we have submitted the required documents referring to the letter from PR-II (No.3-l/2019. AD (PR-II) (copies attached).
We are law abiding firm and we duly respect the laws, rules and regulations established by government of Pakistan. We will never do such act that corresponds to breach of laws/ rules and regulations. There are always chances of existence of human error and presence of acetic anhydride in the list of reagents in the method of analysis of Apoclox injection 500mg is an example of that it went undeleted but it really doesn't mean that we are using a banned chemical in our lab. We will never violate the rules. Now kindly dismiss the matter and allow us the regular production of our product. We shall be remaining grateful.
Area FID, DRAP, Lahore was requested vide letter No.F.03-50/2019-QC dated 06-08-2020 and 26-08-2020 to verify the claim by the firm as recorded above and submit conclusive report regarding firm's claims for further consideration by Registration Board.
FID, DRAP, Lahore forwarded the report and is reproduced as under;
The Inspection of M/s PDH Laboratories (Pvt.) Ltd 9.5Km Sheikhupura Road Lahore was conducted on 27-08-2020 with reference to DRAP Islamabad letter No.F.3-50/2019-QC dated 06-08-2020 and even number dated 26-08-2020 on the subject case referred by PQCB Punjab regarding Apoclox 500mg Injection Mfg by PDH Laboratories (Pvt.) Ltd Lahore to verify the claim stated therein:-
The firm management informed the panel and provided documents that they were manufacturing Apoclox 500mg Injection (Ampicillin+Cloxacillin), Registration 007118 since long and also testing it as per their in house testing method
The management informed that they were only using imidazole with buffer for the reparation of solutions for testing as till date as the combined finished product is not available an any pharmacopoeia
The Management also stated that the chemical acetic anhydride which was printed in the list of reagents in the previous testing method was a typographical mistake as the same is not being used in detail in procedure explained in the testing method. A very old SOP of the firm was also shown to the panel in which acetic anhydride was mentioned in the reagents and testing method. Now the management has revised the testing method by removing acetic anhydride from the testing method
It is pertinent to mentioned here that as per available record of import of DRAP, Lahore the firm has never imported acetic anhydride for any purpose. There was no any acetic anhydride stored there, at the time of inspection.
Meanwhile the firm had developed test methods validation protocol for injection Apoclox 250mg and 500mg finished product. However, the firm was given several advise to improve the protocol and

documentation practices.

Conclusion:

Based on the review of the documents at the time of inspection and meetings with the firm's management, it seems that at present, acetic anhydride was not being used by the firm for any purpose as supported by the available import data of the office. Submitted for consideration of the Registration Board, please.

Proceeding and Decision of the 296th Meeting of Registration Board.

Mr. Mohsin Shah (35202-9998661-7) Managing Director & M. Akhtar of M/s PDH Laboratories, Lahore appeared before the Board on behalf of M/s PDH Laboratories to plead the instant case. They submitted before the Board that they have never used the banned chemical acetic anhydride. The name of acetic anhydride in the method of analysis was due to typographic error. In reply to question from Board member, they appraised the Board that they are applying in house specifications for their product.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case, statement given by the firm and report forwarded by the Area FID, DRAP, Lahore decided as follows;

> **"As the matter was investigated through FID, DRAP, Lahore and also there is no utilization of the said chemical i.e. acetic anhydride by the firm and same confirmed by DRAP, Lahore regarding its non-import so the recommendation of Provincial Quality Control Board, Punjab for cancellation Inj. Apoclox 500 mg (Ampicillin+Cloxacillin), Manufactured by M/s PDH Laboratories, Lahore is not entertainable."**

Case No. 11: CASE REFERRED BY PQCB, PUNJAB REGARDING METHOD OF DOSAVIL INJECTION, BATCH NO. AM-182, MANUFACTURED BY M/S DOSACO LABORATORIES.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/FC-1021/6RM/19 dated 20-02-2019 has informed that Director DTL, Lahore reported that they have filed the case pertaining to testing of the drug sample due to non-cooperation of manufacturers. The firm failed to provide product specifications and method of analysis due to which it was not possible to conduct test/analysis of the samples and to report the same in best public interest. The director DTLs have requested the Board to recommend the DRAP for cancellation of registration of the following drug whose product specifications and method of analysis were not provided to the Government Analyst concerned by Pharmaceutical Firm.

Request for case file by	Name of drug	Batch no	Mfg. by	Request dates & Letter No	Reason of case file
DTL lahore	Dosavil Injection	AM-182	M/S Dosaco Laboratories	DPN/6218/DTL 23-11-18 DPN/6335/DTL 19-12-18	The firm failed to provide product specifications and method of analysis

Proceeding and decision:

Subject matter was considered by Provincial Quality Control Board (PQCB) in its 6th retesting meeting held on 20-02-2019. Secretary PQCB appraised the committee about background of the subject matter which was discussed at length. The committee observed that all the manufacturers/drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government analyst/Drug Testing Laboratories as and when required. The need for product specifications /method of analysis becomes more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample without having manufacturer specification / method of test / analysis.

The Committee expressed its serious concerns over casual behavior and non-cooperation on the part

of the above listed firms in this regard. The Committee after detailed discussion and deliberation decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drug listed above, in best public interest.

Proceeding and Decision of 290th meeting of Registration Board.

The case was presented before the Registration Board in its 290th meeting held on 04th July, 2019 and the Board after detailed discussion decided as under:

"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for failing to fulfill the condition for registration by not providing product specifications / testing method."

Show cause notice was served to the firm vide letter No.03-37/2019 (290th RB) dated 26-09-2019 as per decision of the Registration Board.

In response to the above said show cause notice, M/s Dosaco Laboratories , Lahore submitted their reply vide reference No.DS.INJ/10-19 dated 02-10-2019 addressed to Assistant Director (QC-II) regarding the subject cited above wherein they have humbly stated that they have already been submitted product specification and method of analysis of their registered product Dosavil injection to the Director Drugs Testing laboratory, Lahore through TCS on 15-01-2019 vide letter No.DSL/1-19 dated 15-01-2019.

They further stated that all the relevant documents are attached herewith for information and record, please.

Proceedings and Decision of 293rd Meeting of Registration Board.

As no one appeared on behalf of the firm before Registration Board and the Board accordingly decided to give second / last opportunity of personal hearing to the firm/accused in the next meeting.

The above said decision was communicated to the firm vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020.

Proceeding & Decision of the 296th meeting of Registration Board.

Mr. M. Aslam Javed (0345-4233784), Advocate appeared before the Board on behalf of M/s Dosaco laboratories to plead the instant case. He submitted that while the letters were issued to them by the PQCB, Punjab their unit was closed. There were also some GMP observations and sudden death of their owner was also a major problem. He further assured that in future they will show full co-operation.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case, statement given by the firm decided as follows;

"Suspended the Registration of Dosavil Injection, Reg. No.011233, Manufactured by M/s Dosaco Laboratories, Lahore for 03 months."

Case No. 12: CASE REFERRED BY PQCB, PUNJAB REGARDING PROVISION OF NUGATORY METHODOF INJ. COLIMOXIN TO DTL, BAHAWALPUR BY M/s SELMORE PHARMACEUTICALS.

The Secretary, Provincial Quality Control Board, Punjab vide reference No. PQCB/ISU-2-DTL-B-206/19 dated 23-05-2019 wherein he has informed that Director DTL Bahawalpur vide letter no. 485 dated: 01-03-19 stated that DTL has received the updated method of Inj. Colimoxin (100ml) manufactured by M/S Selmore Pharmaceuticals (Pvt.) Ltd. Approved by the PQCB but there is a deficiency in newly updated method as micro-assay test of Colistin Sulphate is not working. Personal hearing notice served to the firm on 25-03-2019.

The Secretary, PQCB, Punjab informed that subject issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs /Act 1976 in its 203rdmeeting held on 29-03-2019. Representative of M/S Selmore Pharmaceuticals (Pvt.) Ltd appeared before the worthy Board to explain their position before the Worthy Board. He stated that their provided method is validated and give results for their sample as well standard. The matter was discussed by the Board at length. The Board after discussion decided to direct the Government Analyst, DTL Bahawalpur to test/analyze of

the drug sample with no deviation from the provided method, in the presence of Quality Control Incharge of the firm who will provide technical assistance to the Government Analyst.
The Secretary, PQCB, Punjab further informed that now, Director DTL Bahawalpur vide letter no. 871 dated: 13-05-19 stated that upon the recommendation of worthy Board the test/ analysis was performed on 04-05-19 in the presence of microbiologist from M/S Selmore Pharmaceuticals. The letter of satisfaction of microbiologist about laboratory conditions and method application in writing form was taken.
It was concluded that lower dilutions of sample and standard 1250 lU/ml exhibited no clearly defined zones of inhibition and multiple numbers of bacterial colonies were seen adjacent to wells. Higher dilutions of sample and standard 2500 lU/ml exhibited very minute zones of inhibitions having mean diameter of 10.625 mm and 11.360mm respectively while 8 mm is the size of well. It was impractical to calculate the final potency of the colistin sulphate in the Colimoxin injection 100 ml due to absence of zones of inhibition in lower dilution sample and standard dilutions. Due to provision of nugatory method to Drug Testing Laboratory Bahawalpur by M/S Selmore Pharmaceuticals, the worthy Board is suggested to review the registration of the product.
The matter is placed before the worthy Board for further discussion and necessary action.

CURRENT PROCEEDINGS & DECISIONS BY THE BOARD IN 206th MEETING HELD ON 23-05-19

Subject issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 206th meeting held on 23-05-19. Secretary PQCB apprised the Board about background of the subject matter which was discussed at length. Secretary PQCB further apprised the Board that Inj. Colimoxin is a combination of Amoxicillin as Trihydrate and Colistin Sulphate which is not available in any official pharmacopoeia. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and effective method of analysis to the Government analyst/Drug Testing Laboratories. The need for product specifications /effective method of analysis become more critical when the drug is not available in official pharmacopoeias and/or the manufacturer nas its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample on such method provided by the firm, which do not work in the Laboratory/ nugatory. The Board expressed its serious concern over casual behavior on the part of the firm in this regard.
The Board after due discussion and deliberation unanimously decided to recommend DRAP for the cancellation of registration of the above mentioned product as the manufacturer provided nugatory method to the DTL Bahawalpur.

Decision of 293rd meeting of Registration Board.

Registration Board after detailed discussion decided to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for providing nugatory method of analysis of the product in question to the Drugs Testing Laboratory, Bahawalpur."

Show cause notice as per decision of the Registration Board was issued to the quarter concerned vide Letter No.F.03-65/2019-QC (293rd RB) dated 21-04-2020 but the reply of the firm is yet not received. In response to the above said show cause notice, the firm submitted their reply vide reference No. nil dated 11-05-2020 and is reproduced as under;
In response to this show cause notice, and remarks about validity of method of the product, we submit as under:

1. *Our product is fully compliant with all specifications and as per the impugned report of DTL Bahawalpur the product has been allegedly declared to be substandard on the basis of Assay hence the product colimoxin's method is called in question by the DTL Bahawalpur due to purportedly providing ineffective nugatory method to the DTL Bahawalpur, whereas the company's repute is at risk.*
2. *M/s Selmore is one of the prominent Pharmaceuticals Company in manufacturing quality and life saving drugs all over in the Pakistan and even outside of its territories. The company's first and foremost manifesto is to save life of human, species being by providing up to the mark and quality*

product in the market for which the company abide by the rules, regulations of international standard cGMP as well as stick by local laws of the land.

3. *Its been more than ten years, we are manufacturing this product and marketed hundreds of batches of Colimoxin Injection (for veterinary use only) but no complaint of any sort is reported expect DTL Bahawalpur even repeatedly, whereas the same Batch No. CM-212 was declared of standard quality by adopting the same procedure and method by the Govt. Analyst from DTL Multan, DTL Faisalabad as well as from NIH Islamabad positively (copies of reports are attach herewith). Therefore, we reiterate that the product Colimoxin Injection is of a standard quality product according specifications and provided method.*
4. *To maintain the supply and harmony between the company and institution, we gave replacement of the product Colimoxin Injection Batch No. CM-225 without considering monetary loss and just to keep the company moving ahead towards its vision but the same was rejected again being sub-standard. Later on it was declared upto the mark and standard quality product by NIH Islamabad (copy of testing report attached). So there may be possibility in adopting the method of the product Colimoxin Injection through and through by DTL Bahawalpur, as per the company's specification and method inadvertently.*

5. *We have maintained in house validation of the product Colimoxin Injection with expertise as the company has invested much to keep the lab update and carries best lab equipment's of the world and even hold R&D department with its wider, for the assurance of the product quality and stability (validation documents are also attached herewith).*

6. *After DTL Bahawalpur reports, we have manufactured a number of batches of the product Colimoxin Injection by applying the same method as per previous one and supplied in various institutions and all batches were declared of a standard quality and no one raised any objection regarding method of the product (copies of reports are attach herewith).*

7. *As for as latter of satisfaction is concerned by the company representative regarding DTL Bahawalpur we have written a detailed letter to the Secretary PQCB Punjab Lahore in which we have described the whole scenario regarding testing procedure of analyst of DTL Bahawalpur (copy is attached for your kind perusal).*

8. *Colimoxin Injection is the combination of Amoxicillin as trihydrate and Colistin Sulphate but sir for the Bio-assay Penicilinase Enzyme is used as Amoxycillin Inhibitor (P-Lactamase).*

Reference:

a- USP/Sterility Test Chapter <71>

b- *https://www.fda.gov/fdes/abont%020fda/piiblished/Pharmaceiitical-Microbiolosy-Manual.pdf*

Keeping in view, all above mentioned facts you are humbly requested to please! Consider our position that we used a validated method for the testing of Colistin sulphate in Colimoxin Injection and all Govt, reports are endorsing this point, stating the Colimoxin Injection as of standard quality. So we asserted that the Colimoxin Injection is of standard quality product which never ever cause harm to any single species so for since its registration, its may be just a little bit confusion in adopting the process which could be take off.

Therefor it is humble requested that the product Colimoxin Injection may kindly not be suspended or cancelled or any other action should not be taken in any way in the interest of justice and equity.

Having submitted the above, we wish to request for personal hearing to clear more of our position in this regard.

Proceeding & decision of 296th Meeting of Registration Board.

Mr. Muhammad Ijaz (35200-1460474-3), Quality Control Manager & Muzaffar Iqbal (0300-8425925), Manager regulatory Affairs appeared before the Board on behalf of M/s M/s Selmore Pharmaceuticals (Pvt.) Ltd., Lahore to plead the instant case. He submitted before the Board that they have manufactured batch No. 206 to 215. Batch No. 212 was declared as of standard quality by DTL, Faisalabad & Multan while DTL, Bahawalpur declared the said batch as of substandard quality. The firm challenged the report of DTL, Bahawalpur and NIH, Islamabad declared the said batch as of standard quality. the same batch along with other batches of the same product have been declared by the NIH, Islamabad as of standard quality. Once again Batch No. 225 was declared as of substandard

quality by the DTL, Bahawalpur and the firm again challenge the report of DTL, Bahawalpur. NIH, Islamabad again declared the said product as of standard quality. They submitted before the Board that after DTL Bahawalpur reports, they have manufactured a number of batches of the product Colimoxin Injection by applying the same method as per previous one and supplied in various institutions and all batches were declared of a standard quality and no one raised any objection regarding method of the product.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case, statement given by the firm decided to refer back the case to Provincial Quality Control Board, Punjab and to verify the statement of the firm.

Case No. 13: CASE REFERRED BY PQCB, PUNJAB REGARDING NON-PROVISION OF METHOD OF ANALYSIS AND STANDARD BY MS LAWARI PHARMACEUTICALS FOR POLWARI 100MG TABLET.

Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/ISU-5-DTL-M-209/19 dated 17-07-2019 has informed that Director Drug Testing Laboratory, Multan reported that they have to file the cases pertaining to testing of Tab. POLWARI 100 mg due to non provision of method of analysis and standards by the firm despite of multiple requests i.e. 5594/DTL Dated 9/4/19, 620/DTL Dated 17/4/19, 645/DTL Dated 22/4/19, 653/DTL Dated 24/4/19, 686/DTL Dated 29/4/19.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject issue was considered by the Provincial Quality Control Board, under action 11 of the Drugs Act 1976 in its **208th meeting held on 27-06-2019.** Government analyst DTL, Multan apprised the Board that the firm did not responded despite of multiple requests by the DTL Multan for provision of method of analysis and standards. The Board after detailed discussion and deliberation decided to issue show cause/personal hearing notice to M/s Lawari Pharmaceuticals to appear before the Board in next meeting of PQCB.

Personal Hearing notice dated 8th July, 2019 was served to the firm.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was considered by Provincial Quality Control Board (PQCB) in its 209th meeting of Provincial Quality Control Board held on 17-07-2019. No one appeared on behalf of the firm although a personal hearing notice was served to the firm. Secretary PQCB appraised the Board about background of the subject matter which was discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specifications and method of analysis to the Government analyst/ Drug Testing Laboratories as and when required. The need for product specification/method of analysis become more critical when the drug is not available as monograph in official pharmacopeias &/or the manufacturer has its own customized specifications/method of analysis. In such circumstances it become quite challenging &/or almost impossible for a Government Analyst to conduct testing of the drug sample.

The Board expressed its serious concerns over casual behavior and non-cooperation by the above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the Provincial Drug Testing Laboratories to file the above-mentioned cases. ***Furthermore, the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drugs enlisted above, in best public interest.***

Decision of 293rd meeting of Registration Board.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for not providing the method of analysis & standards despite of multiple requests by the Drugs Testing Laboratory, Multan."

Show cause notice as per decision of the Registration Board was issued to the quarter concerned vide Letter No.F.03-65/2019-QC (293rd RB) dated 21-04-2020.

In response to the above said show cause notice the firm submitted their reply vide reference No.LI/04/20 date 30-04-2020 and is reproduced as under;

"With reference to your letter No.FN003-65/2019-QC (293rd RB) Dated 21st April 2020 Letter

No.PQCB/VAC-342/19 Dated 8 July 2019 from Provincial Quality Control Board issue to our firm for personal hearing schedule to be held on 17/07/2019 at 10 AM. The personal notice has been received by our firm on 18/7/2019 by receiving late dated notice we replied to provincial quality control board through our letter no. LI/PO.CB/19- 01 dated 19/7/2019 dispatched through LCS receipt no. ST34425902.2 letter arid receiving from UMS attached for your consideration and record purpose.

As per law we haven't received manufacturer portion / any information from the concern Drugs inspector regarding our product Polwari 100mg Tabs Batch No. 265 which is clear violation of Drug Act 1976. And not any letter received from DTL Multan.

It is humble request to registration Board that to file our case.

Thanking you and assuring you best of our cooperation at all the time.

All the evidence regarding this matter is enclose for your ready reference.

Proceedings & Decision of 296th Meeting of Registration Board.

Mr. Waseem Jawaid (61101-7844999-9), Owner of M/s Lawari Pharmaceuticals appeared on behalf of the firm to plead the instant case. He reiterated the points already recorded above in their reply to show cause notice. He further submitted that the personal hearing letter from PQCB, Punjab was received to them after the date of meeting and also showed the record of post office.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case, statement given by the firm decided to refer back the case to Provincial Quality Control Board, Punjab and to verify the statement of the firm.

Case No. 14: **Manufacture & Sale of Sub-Standard Cotton Bandages B.P Type-II, Batch No. CBB-17L047 By M/S The National Absorbent Cotton Mills Co., Karachi.**

The FID-IV, DRAP, Karachi visited the premises of M/s National Absorbent Cotton Mills Co, A-37, S.I.T.E, Karachi on 26-12-2017 and took the that the sample of Cotton Bandages B.P Type-II, Batch No. CBB-17L047, manufactured by M/s The National Absorbent Cotton Mills Co., Karachi for the purpose of test/analysis on prescribed Form-3. Details are as under:

Sr. No.	Name of Drug	Reg. No.	Batch No.	Manfg. Date	Expiry Date	Purported to be manufactured by
01	Cotton Bandages B.P Type-II	066959	CBB-17L047	Nov.17	Oct.19	M/s National Absorbant Cotton Mills Co, A-37, S.I.T.E, Karachi.

A sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for test/analysis vide memorandum No. SHM-24-25/2017- FID-(K-IV) dated 27-12-2017.

The sealed portion of the said sample was also sent to Chairman, Central Licensing Board, DRAP, Islamabad vide letter No.SHM-24-25/2017- FID-(K-IV) dated 27-12-2017.

The Federal Government Analyst, Central Drugs Laboratory, Karachi vide test report No.KQ.692/2017 dated 21st February 2018 declared the sample as of **"Substandard"** quality under the Drugs Act, 1976. Results of the CDL, Karachi test report are reproduced as under:

Description:	*Open wove bandage consist of fabric of plain weave. It is practically odorless, reasonably free from weaving defects and contains not more than traces of leaf residue seed coat and other impurities. It is in one continuous length. The edges are cut evenly parallel to the wrap threads.*	
Fibre identification test:	*Complies.*	
Threads/10cm:	*Determined.*	*Limits:*
Wrap:	*139*	*135 -163 Complies.*
Weft:	*80*	*84 – 96.* ***Does not comply.***
Weight per Unit Area:	*43gm/m^2*	*Not less than 33gm/m^2 Complies.*

The firm didn't agree with the result of CDL, Karachi and requested for retesting from Appellate laboratory, NIH, Islamabad under section 22(4) of the Drugs Act, 1976. On the request of the firm,

sample was sent for retesting from Appellate laboratory, NIH, Islamabad dated 13-11-2018 under section 22(4)&(5) of the Drugs Act, 1976. The Appellate laboratory, NIH, Islamabad vide their test report No. 029-M/2018 dated 26-12-2018 has also declared the sample as of substandard quality. Results of the Appellate laboratory, NIH, Islamabad are reproduced as under:

Description: *Cotton cloth of plain weaves, bleached not to a good white, in one continuous length containing joins and having weaving defects. The edges are not evenly cut parallel to the wrap threads and have loose threads. (Does not comply with BP 1988 which states that cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shells. The edges are evenly cut, parallel with wrap threads, and are reasonably free fron loose threads.)*

Identification: *Cotton Fibers identified.*

Size: *Determined: 10.02cm x 3.03m.* *Limit: 1cm x 3m.*
Complies with the size stated on the label.

Threads per stated length:

	Determined:	*Limit:*
Wrap:	*138 threads/10cm*	*Average 135-163threads/10cm.*
Weft:	*75 threads/10cm*	*Average 84-96 threads/10cm.*

Does not comply with BP 1988.

Weight per unit area: *Determined: 45.60gm/m^2* *Limit: Minimum 33.0gm/m^2*
Complies with BP 1988.

Water soluble and other soluble substances:
Determined: 1.096% *Limit: Not more than 1.5%.*
Complies with BP 1988.

Fluorescence: *Complies with BP 1988.*

In the opinion of the Undersigned the sample is of Substandard quality as defined in the Drugs Act, 1976 for the reasons given below:

Description: *Cotton cloth of plain weaves, bleached not to a good white, in one continuous length containing joins and having weaving defects. The edges are not evenly cut parallel to the wrap threads and have loose threads. (Does not comply with BP 1988 which states that cotton cloth of plain weave, bleached to a good white, in one continuous length containing no joins, clean, and reasonably free from weaving defects, leaf and shells. The edges are evenly cut, parallel with wrap threads, and are reasonably free fron loose threads.)*

Weft: *75 threads/10cm* *Average 84-96 threads/10cm.*
Does not comply with BP 1988.

The FID, DRAP, Karachi submitted that in light of the CDL, test report and appellate laboratory, NIH Islamabad test reports, M/s National absorbent cotton mills Co, A-37, S.I.T.E, Karachi is involved in manufacturing and selling of substandard drug " Cotton Bandages" B.P Type-II, Batch No.CBB-17L047, which is violation of section 23 (1) (a) (v) of the Drugs Act, 1976 and DRAP Act, 2012 and rules farmed there under and view of the said violation action may be initiated under section 42 of the Drugs Act, 1976 and rules farmed there under.

Names of responsible provided by the firm to FID-IV, DRAP, Karachi are as under and also verified by the Division of Medical Devices & Medicated Cosmetics.

Name	Designation	CNIC
Mr. Kashif Iftikhar	Chief executive Officer	42201-1503654-5
Mr. Altaf Hussain	Production Incharge	42501-8564360-3
Mr. Liaqat Ali	Quality Control Incharge	43207-3743073-5

Show cause notice was issued to the firm and above accused along with the copies of CDL, Karachi and NIH, Islamabad test reports under section 7 (11) of the Drugs Act, 1976 vide letter No.F.03-11/2018-QC dated 06-07-2020 for the following actions:

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

In reply to the above said show cause notice M/s The National Absorbent Cotton Mills Co. submitted their reply vide reference No.NACM/GM/044/20 dated 15-07-202 and is reproduced as under:

"We refer to your letter No.F.03-11/2018-QC dated 06th July 2020 received on 09-07-2020 concerning the subject matter and hereby enclosed previous correspondence and comparison report containing test results including complies and variances in the test reports with comparison of standard requirements for your perusal.

We would like to inform you that since day first our top management and technical staff was fully involved and in close coordination with local FID officials on proper resolution and settlement of the above matter and very thankful for them on providing guidance and support not only improvement of quality control & Assurance process but also in advancement of machinery etc.

During the period from the sample taken from our factory premises in December, 2017 till to date we have satisfactorily gone through GMP visit and panel visit conducted by experts from DRAP who have given "Satisfactory" rating in their report and based on that we received our medical device manufacturing license whose credit definitely marked to them. Further, we have also received satisfactory report from Central Drug Laboratory report dated 08-02-2019 against sample of cotton Bandages B.P. type II (Batch No. CBB-19A001)

Nevertheless, we are very much understand the importance of quality and very rigorously complying GMP practices in the whole process and will ensure our best without any quality compromise in future. In view of the above you are kindly requested to appreciate our efforts towards improvements in all areas and give us a favorable consideration in this matter.

Nonetheless we understand that all the efforts have been made since December, 2017 to-date towards improvements and achievements in process and product quality for your complete satisfaction. However, if you feel that these improvements needs to be presented in person then I kashif Iftekhar, CEO, would like to avail this opportunity to appear in person and request you to withdraw the show cause notice.

We assure you our best efforts and will furnish any information you may require in this matter."

Proceeding & Decision of 296th Meeting of Registration Board.

No one appeared before the Board on behalf of M/s National absorbent cotton mills Co, A-37, S.I.T.E, Karachi in the instant case and the Board decided to give second chance of personal hearing to the firm and accused.

Case No. 15:- Manufacture And Sale Of Spurious Drug (Quinozef 250mg Tablets, Batch No. AP0014) – M/S Ambro Pharma (Pvt.) Ltd., Islamabad.

That the FID-I,DRAP, Islamabad stated that he has been notified as a Federal Inspectors of Drugs for area jurisdiction of Industrial Triangle Kahuta Road Islamabad since 31st May, 2018 vide S.R.O. 686 (I)/2018.

That the Federal Government Analyst, Central Drugs Laboratory(CDL) Karachi declared the following sample as **"Spurious"** vide test analysis report No.NAS.111/2018 dated 14.11.2018. The sample was sent by Drug Inspector, Gilgit Baltistan (GB) vide memorandum No.103/DI-GLT/97/298 dated 23.10.2018 to CDL.

Name of Drug	Reg. No.	Batch No.	Date/Mfg	Date/Exp	Claimed to be Mfg By
Quinozef 250mg Tablets	046368	AP0014	08-17	08-20	M/s Ambro Pharma Pvt. Ltd., Islamabad

That Assistant Director (Quality Control) vide letter No.04-74/2018-QC dated 26th November, 2018 conveyed the undersigned about the above said report with the request to look into the matter and submit complete investigation. Undersigned along with FID-IV visited the firm on 26th November, 2018 on the direction of Additional Director, QA&LT. The panel noticed number of serious GMP violations during the inspection. The report was submitted to the Additional (Director), QA&LT vide letter No.F.3-7/2003-FID–I (ISD) dated 28th November, 2019 with the recommendation to carry out a thorough investigation for manufacturing of spurious drugs and inspection of firm by a larger panel (in order to cover all facets/aspects mentioned in the report) and to probe the matter more carefully.

That in response to the above, AD (QC) vide letter No.04-74/2018-QC dated 30th November, 2018 conveyed the approval of following panel to conduct thorough inspection of firm by the competent authority to probe the manufacturing of Spurious product Quinozef (Ciprofloxacin) 250mg Tablets Reg. No. 046368 Batch No.AP0014 and to see overall GMP compliance (Annex - E):

a) Mr.NadeemIqbal, Expert member
b) Mr. Abdul SattarSohrani, Additional Director, QA&LT
c) Mahvash Ansari, FID-IV/DD (QC), QA&LT, DRAP.
d) Area Federal Inspector of Drugs, DRAP, Islamabad.

That the inspection was conducted by the above panel on 03rd December, 2018 and again a number of violations were noticed and conveyed to Secretary, Central Licensing Board and Secretary, Registration Board via the inspection report vide letter No. F.3-7/2003-FID-I dated 24th December, 2018 (Annex - F). It is pertinent to mention here that DML of the firm was cancelled by Central Licensing Board on the basis of gross violations as reported above.

That during the inspection, undersigned took following samples on form-3 (Annex - G) for test/analysis and sent to Federal Government Analyst, CDL, Karachi vide memorandum No.F.3-7/2003-FID-I dated 07th December, 2018 (Annex - H).

Name of Drug	Reg. No.	Batch No.	Date/Mfg.	Date/Exp.	Claimed to be Mfg. by
Quinozef (Ciprofloxacin) 250mg Tablets	046368	AP0014	08/2017	08/2020	M/s Ambro Pharma Pvt. Ltd., Islamabad
Polymal-F Tablet (Iron III hydroxide polymatose complex 100 mg + Folic acid 350 mcg)	045897	AP0028	04/2018	04/2020	-do-

That Federal Government Analyst (FGA), Central Drug Laboratory, Karachi vide test reports No.R.IP.309/2018 dated 11th January, 2019 (Annex - I) declared the drug mentioned at S.No.1 in above table, as **Spurious** with the remarks that the sample is under section 3 (z-b) (i) of the Drugs Act, 1976. While the drug mentioned at S.No.2 in above table, declared as "Standard" by the FGA vide test reports No.R.IP.310/2018 dated 09th January, 2019 with the remarks that "the sample is of standard quality with regard to the tests performed". Results of the test report are reproduced as under:

Description: *Yellow colored oval shaped film coated with line of bisection on one side.*
Identification: *Ciprofloxacin Hydrochloride NOT Identified.*
Remarks: *The sample is under section 3 (z-b) (i) of the Drugs Act, 1976.*
Note:

1) *The HPLC and FTIR studies show that the sample contains Levofloxacin (237.3120 mg/tablet) instead of ciprofloxacin HCl as stated on the label.*

2) Section 3 (Definition):In this act unless there is anything repugnant in the subject or context 3 (z): "Specification" when applied to a drug:

3 (z-b): Spurious drug means a drug:

i. Which purports to be a drug but does not contain the active ingredient of that drug

The Assistant Director (Quality Control) again requested the undersigned to look into the matter and submit a complete case for further consideration by the concerned Board vide letter No.04-74/2018-QC dated 18th January, 2019. The said reports (certificate of test or analysis) were forwarded/delivered to the firm as required under section 22(3) (a) of Drugs Act, 1976 vide letter No.F.3-7/2003-FID–I (ISD) dated 12th February, 2019. The firm was asked for explaining its position in this regard.

M/s Ambro Pharmaceuticals, Islamabad through its owner Mr. Abdul Majeed Chaudhary replied vide letter No.APL/FID-003/2018-19 dated 19th February, 2019 stated that:

> "…..they are not satisfied above Analytical Report of our product as declared "Spurious". Now, we have challenged in the Appellate Laboratory i.e. National Institute of Health, Islamabad, because we tested our product in Quality Control Laboratory, as per our Q.C. Lab. report the sample is declared up to standard as a Ciprofloxacin. You are requested to kindly send samples of our product to National Institute of Health for further testing please".

In the light of the firm's above request, the Board portion was sent for appellate testing under section 22(5) of Drugs Act, 1976 to Appellate Board. The Appellate Laboratory, NIH, Islamabad also declared the said sample as **"Spurious"** vide test report No.016-M/2019 dated 19th July, 2019. Results are reproduced as under:

Description: *Yellow colored oblong shaped, biconvex, film coated tablets having bisectional line on one side whereas plain from the other side packed in blister packing further contained in an outer carton along with leaflet.*

Identification: *Ciprofloxacin not identified.*
Levofloxacin identified.

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

Does not comply with manufacturer specifications and official pharmacopoeia.

In the opinion of the undersigned the sample is of spurious as defined in the Drugs Act, 1976 for the reasons given below:

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

During investigation, original warranty and bill invoices confirming the sale/trading of drug under question to Gilgit Baltistan from stock register were traced. It has now proved that product under question was manufactured by M/s Ambro Pharmaceuticals, Islamabad and following persons are responsible for the offence:

a) M/s Ambro pharmaceuticals, Islamabad through owner Ch. Abdul Majeed.

b) Ch. Abdul Majeed, (claimed) Owner of firm.
c) Mr. Muhammad Asif Awan, Production Manager.
d) Ms. Rohi Asif, Quality Control Manager.

That in the light of substantial evidence, it is therefore, requested to grant permission for registration of FIR or direct prosecution in the competent Drug Court against the above mentioned persons responsible for violation of Schedule-II (1) (a) (i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.

Proceeding and Decision of 292nd meeting of Registration Board.

The case was presented before the Registration Board in its 292nd meeting held on 01st – 02nd October, 2019 and the Board considered and evaluated the following record:

- Test report No.NAS.111/2018 dated 14th November, 2018 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 28th November, 2018 by FID-I, DRAP, Islamabad.
- Test report No.R.IP.309/2018 dated 11th January, 2019 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 24th December, 2018 by FID-I, DRAP, Islamabad.
- Test report No.016-M/2019 dated 19th July, 2019 by the Appellate laboratory, NIH, Islamabad.
- Complete case forwarded by FID-I, DRAP, Islamabad vide No.F.3-7/2003-FID-I dated 23rd September, 2019.

The Board after detailed discussion and deliberation decided as under:

- To serve show cause notice and personal hearing to the firm and responsible persons for manufacturing and sale of Spurious Drug Quinozef 250mg Tablets, Registration number 046368, Batch No. AP0014, manufactured by M/s Ambro pharmaceuticals, Islamabad in violation to Schedule-II (1) (a)(i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.

As per decision of the Registration Board, show cause notice was served to the firm and accused vide letter No.F.03-46/2019-QC (292nd RB) dated 08-11-2019.

Reply of the firm is still awaited.

Proceedings and Decision of 293rd Meeting of Registration Board.

No one appeared on behalf of the firm before the Registration Board in its 293rd meeting held on 08-01-2020 and the Board was appraised that the personal hearing letters were received back undelivered. The Board considered and evaluated once again the following record:

- Test report No.NAS.111/2018 dated 14th November, 2018 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 28th November, 2018 by FID-I, DRAP, Islamabad.
- Test report No.R.IP.309/2018 dated 11th January, 2019 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 24th December, 2018 by FID-I, DRAP, Islamabad.
- Test report No.016-M/2019 dated 19th July, 2019 by the Appellate laboratory, NIH, Islamabad.
- Complete case forwarded by FID-I, DRAP, Islamabad vide No.F.3-7/2003-FID-I dated 23rd September, 2019.

The Board after detailed discussion and deliberation decided to grant permission of prosecution against the following accused persons in the court of competent jurisdiction for violating the provisions of Schedule-II(1)(a)(i) of the DRAP Act, 2012 read with Section 23(1)(a)(i) of the Drugs Act, 1976 punishable under Schedule-III(1)(a) of the DRAP Act, 2012 read with Section 27(1)(a) of the Drugs Act, 1976:

a) M/s Ambro pharmaceuticals, Plot no. 293, Industrial Triangle, Kahuta Road,Islamabad through owner Ch. Abdul Majeed.

b) Ch. Abdul Majeed, (claimed) Owner of firm (CNIC No.: 37405-9697166-9; Cell no.:0300-8555655).
c) Mr. Muhammad Asif Awan, Production Manager.
d) Ms. Rohi Asif, Quality Control Manager.

Board directed the FID to lodge complaint for prosecution against the above mentioned accused persons in the court of competent jurisdiction along with all relevant record and submit compliance report thereof.

Current Status of the Case.

It is submitted that personal hearing letters issued to the firm/accused were received back undelivered and at the same time area FID, DRAP, Islamabad could also not been able to deliver personal hearing letter to the firm. In order to avoid any legal complications and give the accused/firm another & final opportunity of personal hearing, the case is once again placed before the Registration Board for further necessary directions.

Proceedings and Decision of Board in its 295th Meeting

Registration Board considered the facts/available record of the case, and after thorough deliberation decided as under:

- Copies of the CNIC's of the accused shall be obtained from the Drugs Licensing Division as per their available record.
- Personal hearing letters shall be issued again to the accused upon addresses on their CINC's.

The above said decision was communicated to the Additional Director Drugs Licensing Division vide letter No.F.03-28/2020-QC (295th RB) dated 19-08-2020 with request to provide the requisite information for further processing of the case. A copy of letter was also communicated to the concerned FID with request to provide requisite information.

FID-I, DRAP, Islamabad has provided copies of the CNIC's of the accused and personal hearing letters have been issued upon addresses of on their CNIC's as per decision of the Registration Board.

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. M. Asif Awan (54400-59787393), Production Manager and Ms. Rohi Asif, Quality Control Manager of M/s Ambro pharmaceuticals, Plot no. 293, Industrial Triangle, Kahuta Road, Islamabad appeared on behalf M/s Ambro Pharma to plead the instant case. The Board was appraised that personal hearing letter was issued to the owner of the firm on the CNIC address of the owner, as provided by the area FID, DRAP, Islamabad.

They submitted before the Board that the case of spurious drug was unintentional mistake. The sample was also taken in Gilgit & declared as of spurious. NIH, Islamabad also declared the said product as spurious. They also informed the Board that Quality Control Board, Gilgit Baltistan showed displeasure against the careless attitude of the firm and instructed the firm to be vigilant in future, as spurious products are a great threat for general public.

Decision of 296th Meeting of Registration Board.

The Board after detailed discussion and deliberation decided to grant permission of prosecution against the following accused persons in the court of competent jurisdiction for violating the provisions of Schedule-II(1)(a)(i) of the DRAP Act, 2012 read with Section 23(1)(a)(i) of the Drugs Act, 1976 punishable under Schedule-III(1)(a) of the DRAP Act, 2012 read with Section 27(1)(a) of the Drugs Act, 1976:

a) M/s Ambro pharmaceuticals, Plot no. 293, Industrial Triangle, Kahuta Road, Islamabad through owner Ch. Abdul Majeed.
b) Ch. Abdul Majeed, (claimed) Owner of firm (CNIC No. 37405-9697166-9, Cell No. 0300-8555655).
c) Mr. Muhammad Asif Awan (CNIC No. 54400-5978734-3), Production Manager.
d) Ms. Rohi Asif (54401-9646301-2), Quality Control Manager.

The Board directed the FID to lodge complaint for prosecution against the above mentioned accused persons in the court of competent jurisdiction along with all relevant record and submit compliance report thereof.

Case No.16: CASE REFERRED BY PQCB, PUNJAB REGARDING NON-PROVISION OF METHOD OF ANALYSIS BY M/S CREST PHARMACEUTICALS (PVT.) LTD.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/FC-01/215/19 dated 14-12-2019, received on 11-02-2020, has informed that Government Analyst Drug Testing Laboratory, Faisalabad reported that they have to file the cases pertaining to testing of the various drug samples due to non-cooperation of manufacturer. This firm failed to provide methods and standards for test/analysis due to which it was not possible to conduct test/analysis of the samples and to report the same in best public interest.

Sr. N0.	DI Area	DTL	DTL Letter No. and Date	Manufacturer	Product Name	Registration No.	Mf g Date	Expiry Date	Reason
1.	Deputy Drug Controller Wazirab a d	Faisalaba d	10454/DTL/ FSD 15-10-19	M/S Crest Pharmaceuticals (Pvt.) Ltd	Tablet S-Prazole 40mg (Esomeprazole) Batch# 180504	066478	05-2018	05-2020	No response from firm to provide Product Specification & Method of Analysis despite of 2 letters from DTL vide letter no. 10072/DTU FSD dated:27-08-19, 10188/DTL/ FSD dated: 11--09-19 and one letter to CDC, Punjab vide letter no. 10286/DTL/ FSD dated: 19--09-19

PREVIOUS PROCCEDINGS & DECISION BY THE BOARD:

213 Meeting held on 15-11-2019

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act in its **213th meeting held on 15-11-2019. The** Board after due deliberation and discussion decided to give an Opportunity of personal hearing to the above-mentioned firms before recommendation to the DRAP for cancellation t of their products registration.

Personal hearing notice served to the firm.

CURRENT PROCCEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **meeting held on 14-12-2019.** Secretary PQCB apprised the Board about background of the subject matter which was discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government Analyst/Drug Testing Laboratories and Drug Regulatory Authority of Pakistan vide letter no. F. No.03-37/2019-QC(290th RB) dated 26-09-2019 has issued guide under Testing Specifications. The need for product specifications /method of analysis become more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method of analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample without having manufacturer specification / method of test / analysis.

The Board expressed its serious concerns over casual behavior and non-cooperation on the part ofabove listed firms in this regard. The Board after detailed discussion and deliberation decided to

allow the Provincial Testing Laboratory, Faisalabad to file only those cases where Manufacturer Specifications are not provided by respective firm and also not available in official compendia. Furthermore, the Board decided to recommend the Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drug listed above, in best public interest.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for not providing method and standards for test/analysis despite of multiple requests by the Drugs Testing Laboratory Faisalabad."

The above said decision of the Registration Board was communicated vide letter No.03-28/2020-QC (295th RB) dated 19-08-2020.

M/s Crest Pharmaceuticals vide reference No. nil dated 25-08-2020 submitted their reply and is reproduced as under;

Brief Facts.

- *We always used to provide the information, data and reference standard to the DTL's whenever they ask.*
- *In this particular case, DTL asked to provide us the reference standard, method of analysis, validation data with all supporting documents vide letter No. 10072/DTL/FSD dated 27-08-2019 received on 03-09-2019 and 11-09-2019.*
- *We asked our Indian supplier to send us reference standard.*
- *The trade with India was barred in those days due to Indian action on Kashmir (05-08-2019).*
- *No courier service was booking parcels for Pakistan from India in those days and we were discussing alternative ways for the supply of standard with our supplier.*
- *Meanwhile we received another letter from DTL Faisalabad, referring our case to Chief Drug Inspector Punjab on 19-09-2019.*
- *We feel regretted not to arrange reference standard and reply them within two weeks time provide us by DTL Faisalabad.*

Defense

- *The Registration Board issued guidelines under testing Specifications vide letter No.F03-37/2019-QC (290th RB) dated 26-09-2019 and our case is before the issuance of this letter (27-08-2019), hence does not fall under the violation of this letter.*
- *There is no power of Government Analyst mentioned in the Drugs Act, 1976 to write letters to the companies and time frame to reply.*
- *We could not reply to the DTL due to ban on trade with India in those days.*

Keeping in view the facts of the case and ground reality, the Board is requested to graciously with draw this show cause and stop the proceedings against us to meet the end of justice.

Proceeding & Decision of 296th Meeting of Registration Board.

NO one appeared before the Board and Board decided to give another opportunity of personal hearing to the firm.

Case No. 17: **CASE REFERRED BY PQCB, PUNJAB REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE METHOD OF ANALYSIS.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/F-Isu-11/212/19 dated 30-10-2019 has informed that the following manufacturers have not provided the method of analysis for testing of their products by the Drugs Testing Laboratories;

Sr#	DTL	Name of Drug	Batch No.	Manufactured By	Letters sent
01.	Multan	Inj. Murcobal 500mcg/ml	84	M/S Murfy Pharmaceuticals	Three letters were sent dated: 27-07-19, 21-08-19 and 28-08-19

Sr#	DTL	Name of Drug	Batch No.	Manufactured By	Letters sent
02.	Lahore	Irosim Syrup 120ml	S1-017	M/S Simz Pharmaceuticals (Pvt.) Ltd	Two letters were sent dated: 29-06-19 and 13-07-19

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was considered by the provincial quality control board under section 11 of the Drugs Act, 1976 in its 211th meeting held on 30-09-2019. The board decided to left over the matter due to time constraints.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 212th meeting held on 30-10-2019. Secretary PQCB appraised the Board about background of the subject matter which was discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specifications and method of analysis to the Government analyst/ Drug Testing Laboratories as and when required. The need for product specification/method of analysis become more critical when the drug is not available as monograph in official pharmacopeias'&/or the manufacturer has its own customized specifications/method of analysis. In such circumstances it become quite challenging &/or almost impossible for a Government Analyst to conduct testing of the drug sample.

The Board expressed its serious concerns over casual behaviour and-non-cooperation by the above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the Provincial Drug Testing Laboratories to file the above-mentioned cases. Furthermore, the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drugs enlisted above, in best public interest.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the Provincial Quality Control Board (PQCB), Punjab for not providing the method of analysis & standards despite of multiple requests by the Drugs Testing Laboratories i.e. Multan & Lahore."

In compliance to the above said decision of the Registration Board, show cause notices were issued vide No.F.03-28/2020-QC (295th RB) dated 19-08-2020 to the concerned manufacturers.

M/s Murfy Pharmaceuticals (Pvt.) Ltd., submitted their reply vide reference No.MP/DRAP dated 25-08-2020 and is reproduced as under;

"Respectfully stated that method of analysis/product specifications (In House) regarding our product Inj. Murcobal 500mcg/ml had already been submitted to DTL, Multan and they have been testing this product according to the manufacturer specifications.

As a proof attested copy of TRA No/9745/DTL dated 05-11-2009 from DTL, Multan is enclosed herewith.

We never received letter No: 27-07-2019, No: 21-08-2019 and 28-08-2019 from DTL, Multan.

If we had received any letter from DTL, Multan we would have sent them the method of analysis again.

Moreover, we have again submitted the method of analysis/product specifications (In House) to DTL, Multan vide our letter No.MP/DTL dated 22-08-2020.

Besides DTL Multan we enclose herewith the following test reports from different Drug Testing Laboratories to whom we had already supplied the in house specifications/method of analysis of Inj. Murcobal 500mcg/ml.

S. No.	*Test repot No/date*	*Drug Testing Laboratory*	*Specifications*
1	*TRA-9745/DTL Dated: 05-11-2009*	*DTL Multan*	*Manufacturer's Specifications*
2	*TRA-1163/DTL Dated: 15-01-2009*	*DTL Lahore*	*Manufacturer's Specifications*

3	*TRA-7385/DTL Dated: 15-04-2010*	*DTL Lahore*	*Manufacturer's Specifications*
4	*TRA-190/DTL Dated: 01-01-2011*	*DTL Lahore*	*Manufacturer's Specifications*
5	*TRA-27465/DTL Dated: 31-12-2013*	*DTL Lahore*	*Manufacturer's Specifications*
6	*TRA-6926/DTL Dated: 27-12-2016*	*DTL Bahawalpur*	*In House method*

The above referred test report of Inj. Murcobal 500mcg/ml especially the test report of the DTL, Multan proves that we have already provided, the manufacturer's method of analysis/specifications, to DTL Multan in respect of Inj. Murcobal 500mcg/ml.

It is humbly requested that we have not violated any condition of the product registration therefore taking a lenient view the matter may kindly be filed.

We may kindly be given an opportunity to be heard in person."

Proceeding & Decision of 296th Meeting of Registration Board.

Mr. Mian Shafiq-Ur-Rehman (35202-2382981-7), CEO of M/s Murfy Pharmaceutical appeared before the Board to plead the instant case for their product. He reiterated the points already mentioned in their reply to the show cause notice.

Decision of 296th Meeting of Registration Board.

Registration Board after detailed discussion and deliberations considering the facts of the case, statement given by the firm decided to refer back the case to Provincial Quality Control Board, Punjab and to verify the statement of the firm.

Case No. 18: Investigation Of Sub-Standard Megafen 90ml Suspension (Ibuprofen 100mg/5ml) Batch No. 1-526 M/S Albro Pharmaceuticals (Pvt.) Ltd., Lahore Inspection Thereof.

The Additional Director, DRAP, Lahore vide reference No12865/2019-DRAP (L-VII) dated 07-10-19 addressed to the Director QA&LT, DRAP, Islamabad regarding the subject cited above has enclosed the inspection report of M/s Albro Pharmaceuticals, Lahore. The inspection was conducted by panel of inspectors on 30-09-2019 as per verbal directions of Additional Director QA&LT regarding megafen 90 ml Suspension (Ibuprofen 100mg/5ml) Batch No. 1-526, Manufactured by M/s Albro Pharmaceuticals (Pvt.) Ltd., Lahore which was declared substandard by DTL, Rawalpindi, Government of Punjab.

The panel in its report has mentioned that the Quality Analyst Ms. Yasmeen Bano (Pharm-D) performed test in the presence of panel. The working standard used was obtained from M/s Zenith which was tested against USP Standard as per claim of the firm.

The panel has stated in their report that various ambiguities were found in the manufacturing /QC SOPs and actual performance method. Furthermore, following observations are reported;

i. *The Director of the firm informed that the Ibuprofen raw material was purchased from local market and COA provided was of M/s Mahima Life Sciences, India. The quality control raw material analysis record showed that assay of the material was 100%. Other inactive raw materials were also purchased from local market. No Vender qualification or I&E Rules were being followed.*
ii. *In the standard manufacturing SOP of the Megafen Suspension under heading product description " amber color pet bottle of 90ml" was mentioned whereas in actual the firm was using amber colored glass bottles.*
iii. *The mixing time and RMP required for mixing of CMC (suspending agent) and other raw materials were not mentioned, in the manufacturing SOP.*
iv. *The production Incharge informed that the 1000 liter batch size of the product was being manufactured in two parts of 500 liter each, which was not described in SOPs.*
v. *The quality control analysis for assay was performed as per in house testing method, while the said method was available in B.P/USP.*

vi. *For assay single beam spectrophotometer was used double beam was out of order. The HPLC was not used as recommended in BP/USP.*

vii. *In the quality control testing SOP the limit for the assay of bulk specification of suspension was 95%-105% while that of finished product was 90%-110% of the stated amount. The firm was asked to explain the reason of this difference.*

viii. *In the testing SOP under specification heading it was mentioned that "the product complies with USP Specification", where as USP specifications were not being followed and on the label claim "manufacturer specification" was written.*

ix. *As per analysis conducted in the presence of panel on 30-09-2019 the assay of the product was 106%. The firm already conducted assay on 19-08-2019 after receiving the Drug Testing Laboratory report and it was 95.089%. On that basis the firm applied for Appellate Testing. However, at the time of product release, the quality control assay was 102.3%. The specification limit mentioned in the firm's quality control report was 95-105% of the label claim. Almost 11% variation in current testing assay results conducted on 30-09-2019 and 19-08-2019 was noticed.*

x. *No stability testing was performed on this product. The firm was advised to conduct accelerated stability study for the said batch of the product.*

The conclusion given by panel is reproduced below;

> ***"In this preliminary investigation report the panel is of the view that mixing/soaking of the suspension was not proper. No proper time of mixing and RPM were provided. The firm also deviated from SOPs and the mixing of one batch was done in two parts. The quality control testing procedures also required improvements as the variation in assay results were seen. Moreover quality control testing, SOPs were not as per pharmacopeial method, it was also mentioned in last GMP report. The material management of the firm required improvement with respect to vender qualification and I & E Rules 1976."***

Decision of 293rd meeting of Registration Board.

The case was presented before the Registration Board in its 293rd meeting held on 08th January, 2019. The Board was apprised that the firm has provided a copy of test analysis report in which the product Megafen 90ml Suspension (Ibuprofen 100mg/5ml) Batch No. 1-526 M/S Albro Pharmaceuticals (Pvt.) Ltd., Lahore has been declared of Standard quality by the Appellate Laboratory NIH Islamabad and the Board after detailed discussion and deliberation considered the GMP report forwarded by the Additional Director DRAP, Lahore decided as under:

"That QA&LT Division shall process the GMP report forwarded by the Additional Director DRAP, Lahore by its own, as per their prescribed procedure and present it to the Central Licensing Board which is competent forum for this."

The above said decision was communicated to the quarter concerned with request to comply with the decision of the Registration Board.

In the light of the decision of Registration Board, the Quality Assurance Division presents the case before the Central Licensing Board in its 275th meeting.

The Central Licensing Board in its 275th meeting Decided as under;

"After thorough discussion/deliberations, the Central Licensing Board decided to refer back the case to Registration Board for taking decision on the matter. The Board was of the opinion that as the observation noted by the panel of experts are related to specific product i.e Megafen Suspension and these observations are not related to overall GMP compliance. Therefore, relevant Board decided the case in the light of report at their end."

<u>Proceeding & Decision of 296th Meeting of Registration Board.</u>

Registration Board after detailed discussion and deliberations considering the facts of the case, decided to issue show cause notice for cancellation/suspension of registration of the product in question to the firm."

Case No. 19: **CASE REFERRED BY PQCB, PUNJAB REGARDING CAPSULE CAPSOL ZOL 40, BATCH NO. 0198, MANUFACTURED BY M/S FESTAL LABORATORIES, JINNAH INDUSTRIAL ESTATE, LINK KATTARBAND RAOD, LAHORE.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-52/2018 dated 30-10-2019 has informed that Provincial Inspector of Drugs Jampur/Rojhan reported that:

i. He, on 11-01-2018, inspected the business premises of M/s Tahir Medical Store Main Medicine Store, Opposite THQ Hospital Rojhan and took two different drug samples on Form No 4 for the purpose of test/analysis.

ii. One out of these drug samples, after test/ analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Multan, as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Capsule Capsol Zol 40 Esomeprazole 40mg	0198	M/s Festal Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore.	TRA No.01-57000126/DTL dated: 31-03-2018	**Analysis with specifications applied:** USP 2017 **Identification:** Esomeprazole identified. **Assay:** Esomeprazole: Stated 40mg/Cap Determined **48.82mg/ Cap** Percentage **122.04%** Limit 90-110% **Does not comply with the specifications.** **Result:** The sample is Substandard, on the basis of tests performed.

iii. M/S Tahir Medical Store Opposite THQ Hospital Rojhan provided Invoice/ warranty No.7103196 dated 01-01-2018 issued by M/S ALM Pharma Mahmood Abad Colony Street # 5 Khanewal Road, Multan who in turn provided invoice/warranty No. 3486 dated 29-04-2017 issued by M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore as a proof of their purchase of the said drug.

iv. A copy of Test report and Warrantor portion of drug sample was sent to M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore and they were asked to explain their position and provide requisite information in this regard.

v. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing for sale/Sale of sale of Substandard drug**

b. **issuance of false warranty**

Show cause/personal hearing notice(s) issued to accused person(s)

Reply of the Firm:

M/s Festel laboratory stated that we have checked our retained sample but we find the results within the limits i.e 107% further more your DTL declare the weight variation is within the limits. How it is possible that the assay exceeds the limits other this fact we done our production on automatic machines if we fill this shell 3 manually by force the maximum assay goes up to 108% we cannot fill the pellets more than 108% then how it is possible that assay exceed 110%.

Furthermore, our product is according to company's specification and DTL have checked the product according to USP Specifications.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **196th meeting held on 13-11-2018.** Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons.

Representative of the firm appeared before the board and stated that according to Report of Govt. Analyst DTL Multan the subject drug sample was tested according to U.S.P Specifications however our product is registered as Festel Specifications. We have checked our retained sample and found the results within stated limits i.e 107%. Moreover, Weight variation of subject drug sample was found within limits according to the DTL Report so the assay of the active drug cannot exceed the limits as manufacturing plant is fully automated. We cannot fill the pellets of drug more than 108% then it is impossible for the assay of the product to exceed 110%.

The Board unanimously decided to constitute an inspection committee comprising of the followings to conduct **Product Specific Inspection (PSI)** of **M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore,** and submit report for consideration by the Board:

Prof. Dr. Mahmood Ahmed Member
Member PQCB
Mr. Munawar Hayat Member
CDC Punjab
Area **Drug Inspector Industries** Facilitator

PRODUCT SPECIFIC INSPECTION (PSI) REPORTOF M/S FESTEL LABORATORIES

Date of Inspection: 25-07-2019

Premises:

Unit started in 2006. Total area (06 Canals), covered area 75% of total). The firm has nine production Sections

1. General Tablet Section.
2. General Capsule Section.
3. General Liquid Section.
4. Psychotropic Section.
5. Eye Drop Section.
6. External Preparation Section.
7. Pyodine Section.
8. Dry powder Suspension (Cephalosporin Section).
9. Dry powder capsule (Cephalosporin Section),

Drug:

Capsol-Zol (Esomeprazole 40mg capsule). Batch No. 0I98
Date of Mfg. 03/2017
Exp. Date 02/2019.

Staff:

Designation	Name
Managing Director	Amir Jahangir
Production Manager	Maqsood Ul Haq
QC Manager	Mubashir Bashir
Warrantor	Akbar Ali

Observations:

DTL Lahore declared substandard on above than the upper limit of assay basis.

1. Product Specification of Capsol- Zol is Manufacturer Specification but it has been present in U.S.P from 2016 but manufacturer still applying its own Specifications.
2. Identification by UV spectrophotometer by the firm for assay.
3. Assay in final release report is 101%
4. One HPLC and one UV Spectrophotometer are available. FTIR not available.
5. IPQC: Weight variation, physical and average weight was performed.
6. Raw material testing performed.

7. Material Test. Vendor source. Vision Pharma, Pakistan
8. Packing Material: Physical testing.
9. Shell testing not performed but started performing from May, 2019.
10. Shift time: 9AM to 5PM.
11. Calibration of UV Spectrophotometer is performed but Internal Calibration not performed on weekly basis.
12. Calibration of Balance performed but calibration certificate docs. not have Confidence limit. Daily calibration record is available from 1st July 2019 to onwards. Calibration of the balance at three different weights showing no deviation even at the fourth decimal point which is astonishing as balance is not in separate cabinet.
13. The weight of the pellets of one capsule was measured during inspection which was I 87mg.
14. The firm not justifies the implementation of the factor in assay of the product.

Batch Processing Record of specific product:

1. BMR Record: available.
2. QC retain sample: available (Wrong Brand Name).
3. Testing method: manufacturer own (U V) method, pharmacopoeial (HPLC) method is not performing.
4. API issued was 25 Kg per batch for 12624 Packs.
5. Batch manufacturing started on 27/03/2017 and completed on 31/03/2017.
6. Batch size: 12624 Packs (finally released 12450 Packs.
7. Production yield: 98.60%.
8. In process QC: Available.
9. Reconciliation sheet: available.
10. Testing of finish product is as per MS.

Conclusion:

The panel is of the opinion that the firm is at fault on the below mentioned POINTS.

1) The firm has produced Certificate of analysis of Esomeprazole raw material which bears expiry date September 2016 whereas; formulation is manufactured on July 2017.
2) The firm has released Esomeprazole in the Quality Control Raw material register without mentioning Batch No., Expiry Date. Manufacturing date and potency of API.
3) In BMR of the said product, it is not confirmed what is the Batch No. of the Raw Material used in manufacturing of the product of that batch.
4) The analysis method of the product was available in USP 2016 on HPLC whereas, the firm is performing the analysis of bulk as well as finished good on manufacturer specification on UV Spectrophotometer.
5) In the filling sheet of the batch manufacturing record shows the wrong data with respect of the time on dated 28-03-17.
6) In Batch manufacturing record blistering date is 29-03-17 whereas the packing date and transfer to finished goods store date is 01-03-17.
7) The firm is printing the name of the product on the label in wrong manner as per registration certificate of the product.
8) FTIR is not available, the release of inactive materials were also in question.
9) The firm was not performing any test on the shell of capsule which is pharmacopeial requirement.
10) The calculation of the assay by the firm with factor is doubtful and not having any official reference.
11) The production and QC Manager of the firm are symbolic, not having any practical experience which is very alarming situation.

The panel is of the opinion that the firm fails to justify the matter, therefore, it is recommended to forward the case to the trial court as well as to DRAP for necessary action in the matter.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976

in its 212th meeting held on 30-10-2019. Mr. Sadiq Hussain Secretary DQCB Rajanpur, was present along with original case file. Dr. Muhammad Munawar Hayat (Member of PSI Committee/ Member of PQCB) briefed the Board about facts of the Product Specific Inspection along with finding and conclusion by the PSI committee. He apprided the Board that the inspection panel is of the opinion that the firm is violating the necessary provision of GMP as required by the Schedule II-B of the Drugs (L.R&A) Rules 1976. The firm used the expired Active Pharmaceutical Ingredients (API) for the manufacture of drug product in question. Moreover, the FTIR was not available with the firm which is essentially required for the identification of the APIs etc. These are the sheer violations of the requirements of the GMP and equivalent to putting the public at the risk of severe/serious adverse event/ mortality/ morbidity.

Secretary PQCB apprised the Board that a letter from the firm M/S Festel Laboratories, Lahore has been received in which they requested to adjourn the case for the next date of hearing as according to them personal hearing notice for the meeting was received on 22-10-2019 and there was insufficient time for them to prepare a suitable defense for the case.

After careful perusal of the above mentioned Inspection report the Board showed serious concerns on GMP violations by the firm. The Board was of the opinion that compliance with Good Manufacturing Practices by the pharmaceutical manufacturers is the best way to ensure quality of medicines being manufactured by them. Such violations/ nonconformance's of GMP guidelines may results in production of compromised quality drugs. The Board after thorough scrutiny of the Product Specific Inspection report observed that that the firm was performing the assay of the finished product on UV-Spectrophotometer. However, the firm was required to adopt the test/analysis method as prescribed in the individual monograph of United States Pharmacopoeia (USP). Whereas the Government Analyst has performed the test/analysis of the product in accordance to the USP specifications through HPLC method. As per the directions of Ministry of Health, Government of Pakistan vide letter No F.3-2/2006-Reg-II-South (M-197) dated 05-06-2006, when a product is contained in any official Pharmacopoeia, then it is mandatory to follow the specifications of that Pharmacopoeia. In present case firm has also violated these direction of Ministry of Health. Moreover, the letter of Personal Hearing was received by the firm eight days before the meeting, so there was sufficient time for them to prepare the defense of the case. Keeping in view the foregoing facts and wilful absence of accused(s), the Board unanimously decided to grant permission for prosecution against the following accused persons in the Drug Court:

1.	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore through its Chief Executive Officer Usman Ghani.	
2.	Usman Ghani	Chief Executive Officer.
3.	Mubarik Ali	Proprietor.
4.	Manzoor Ahmad	Quality Control Manger.
5.	Akbar Ali	Warrantor.
6.	Muhammad Maqsood Ul Haq	Production Incharge.

Of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore , for the offences of:

a. **Manufacturing for sale/Sale of sale of Substandard drug**
b. **Issuance of false warranty**

The Board further decided to suspend the Drug manufacturing License (DML) of the firm for 15 days w.e.f. the date of receipt of this order, with recommendation to DRAP for de-registration of the Product. Moreover, the Board further decided to direct the Area Drug Inspector industries to re-inspect the factory premises after 15 days to evaluate CAPA and remedial measures taken by the firm and submit report to PQCB for further necessary action.

The Provincial Quality Control Board further recommended the Registration Board to deregister the product capsule capsol zol 40 (Esomeprazole 40mg) of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore.

Decision of 293rd meeting of Registration Board.

Registration Board deliberated that PQCB has already prosecuted responsible persons in Drug Court and also recommending DRAP for cancellation of registration. The Board

decided to seek opinion of Legal Affair Division regarding issuance of show cause notice or otherwise.

Current Status of the Case.

In order to comply the above said decision of the Registration Board, The case file was forwarded to the Legal Affair Division for seeking opinion regarding the issuance of show cause notice or otherwise and the reply of the Legal Affair Division is reproduced as under;

"*That the PQCB granted permission for prosecution against the accused persons mentioned in para 8/N and also recommended to DRAP for cancellation of registration of subject product. The Registration Board deferred the matter for opinion of this Division for issuance of show cause notice or otherwise. In view of the above facts, the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.*"

Proceeding and Decision of 295th Meeting of Registration Board.

Registration Board considered the facts of the case and views comments of the Legal Affairs Division, DRAP, Islamabad that the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

"13. *No person-*

(a) Shall be prosecuted or punished for the same offence more than once; or

(b) shall, when accused of an offence, be compelled to be a witness against himself."

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 20: CASE REFERRED BY PQCB, PUNJAB REGARDING SUBSTANDARD MEDIDOL TABLET, MANUFACTURED BY M/S MIDICON PHARMA (PVT.) LTD., PESHAWAR.

Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-278/2018 dated 13-06-2019 wherein he has informed that Provincial Inspector of Drugs Tehsil & district Attock reported that:

i. He, on 16-07-2018, inspected the business premises of Ms/ Hafiz Brothers Medicose Sameer Plaza Attock and took three different types of Drugs on Form-4 for the purpose of test and analysis.

ii. One out of three drug samples , after test/analysis was declared substandard by Government Analyst Drug Testing Laboratory, Rawalpindi as detailed below;

<table>
<tr><th>Name of the Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Report results</th></tr>
<tr><td>Tablet Medidol 500mg [Paracetamol: 500mg, Caffeine:65mg, Chlorpheniramine Maleate:2 mg]</td><td>546</td><td>M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar.</td><td>TRA No.01-13001358/ DTL Dated: 29-10-2018</td><td>Analysis with specifications:
Manufacturer’s specification
Description:
White colored, oblong shaped, biconvex, uncoated tablets engraved word “Medicon” on one side and plain from other side, packed in PVC-ALU blister of 10 tablets.
Identification: Paracetamol, Caffeine and Chlorpheniramine Maleate identified.
Assay:
<table>
<tr><th></th><th>Stated (mg/Tab)</th><th>Determined (mg/Tab)</th><th>%age</th></tr>
<tr><td>Paracetamol</td><td>500</td><td>494.23</td><td>98.85</td></tr>
<tr><td>Caffeine</td><td>65</td><td>62.03</td><td>95.44</td></tr>
<tr><td>Chlorpheniramine Maleate</td><td>2</td><td>1.97</td><td>98.48</td></tr>
</table>
Limit: 90-110%
Dissolution test: (Does not comply with specifications)
<table>
<tr><th></th><th>Average release</th><th>Limit</th></tr>
<tr><td>Paracetamol</td><td>50.75%</td><td>Not less than 75%</td></tr>
<tr><td>Caffeine</td><td>56.87%</td><td>Not specified</td></tr>
<tr><td>Chlorpheniramine Maleate</td><td>212.92%</td><td>Not less than 70%</td></tr>
</table>
The percent release of Chlorpheniramine Maleate is not consistent according to manufacturer’s method.</td></tr>
</table>

				Result: The sample is **substandard** on the basis of dissolution test performed.

iii. M/s Hafiz Brothers Medicose Sameer Plaza Attock provided invoice/warranty No.2037 dated 14-03-2018 issued by M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar as proof of its purchase.

iv. Warrantor portion of the sample was sent to M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar.

v. A copy of test report was sent to M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar with direction to explain their position and provide requisite information in this regard.

Drug inspector requested for grant of permission of prosecution against the nominated accused persons who have contravened the provisions of section 23/27 of the Drugs Act, 1976/DRAP Act, 2012 and Rules framed there under by the way of:-

a) Manufacturing for sale/Sale of substandard drug.
b) Issuance of false warranty.

Show cause/personal hearing notice(s) issued to accused person(s).

Previous proceeding by the Board:

PQCB 205th meeting dated 30-04-2018.

Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act, 1976 in its 205th meeting dated 30-04-2019. Mr Aadil mehmood Secretary DQCB District Attock and Mr. Adnan Aslam Drug Inspector Tehsil Pindi Gheb District Attock was present on behalf of Drug inspector Tehsil Pindi Gheb District Attock with original case record. No one appeared on behalf of M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar. Secretary PQCB appraised the board that written request from Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar has been received stating that owing to the heart problem faced by the Chief Executive of the firm, they requested the Board to adjourn the case.

In view of the foregoing facts, the Board unanimously decided to adjourn the case in best interest of justice. The Board further decided to provide another/final chance of personal hearing to the accused.

Personal hearing Notice issued to the accused persons.

Proceeding & Decision by the Board.

Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act, 1976 in its 207th meeting dated 13-04-2019. Mr Aadil mehmood Secretary DQCB District Attock and Mr. Tariq Masood Shah Drug Inspector Tehsil & District Attock were present along with the original case record. The complete investigation report submitted by the Drug inspector was scrutinized by the Board under section 11(3) (b) of the Drugs Act, 1976. Show-cause was issued to the firm after detail scrutiny and discussion by the Board in accordance to Rules (5) of the Punjab Drug Rules 2007 (as amended). The Board observed that the Drug inspector on 16-07-2018, having Gazette Notification No. S.O (Dental) 10-11/2014 dated 26-03-2015, in exercise of powers conferred to him under section 18 (b) of the Drugs Act, 1976, inspected the premises of Ms/ Hafiz Brothers Medicose Sameer Plaza Attock and took sample of above mentioned Drugs on Form-4 under section 18 (1) (c) (3) of the Drugs Act, 1976 for the purpose of test and analysis. The sample was sent to DTL vide memorandum No.0000017569, dated 21-07-2018, within the prescribed period of seven days as required under section 19 (3) of the Drugs Act, 1976. The drug sample after test and analysis was declared substandard by the Government Analyst, Drug testing laboratory Rawalpindi under section 22 (1) and report was generated on Form no.07 as required under section 22(2) of the Drugs Act 1976. The said sample was tested according to Manufacturer's specifications as mentioned on the label. The instruments used for testing said sample were calibrated. The calibration status and internal calculation sheets were thoroughly checked and scrutinized. On receipt of the report of Government Analyst the Drug Inspector delivered the test report in accordance to section 22(3) of the Drugs Act 1976.The Drug Inspector conveyed warrantor portion of the drug sample vide letter no 225/DI/AK/18 dated 01-08-2018 to M/s Medicon Pharmaceuticals (Pvt.) Ltd, B1/11 Industrial Estate, Hayatabad, Peshawar and DTL report vide letter no. 402/DI.AK/18 dated 15-11-2018 to M/s Medicon Pharmaceuticals (Pvt.) Ltd, B1/11 Industrial Estate, Hayatabad, Peshawar and asked for provision of

requisite information.

Among accused Dr. Maqbool (Managing Director) of M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar was present. Managing Director of the firm appeared before the Board and submitted that chemical assay of the product complies with the specifications. The average release of Chlorpheniramine Maleate is 212.92% which is impossible. He further submitted that the report of Drug Testing Laboratory, Rawalpindi is defective. Their product is registered on Manufacturer's specifications, however, Drug Testing Laboratory, Rawalpindi never asked for provision of method for test/ analysis.

The Board after detailed scrutiny of the record, due deliberation & discussion observed that the Government Analyst, Drug Testing Laboratory, Rawalpindi applied the same method for test/ analysis as provided by the manufacturer. The method provided by M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar is incomplete and the drug sample was declared substandard on the basis of analysis performed according to manufacturer's own method. The chemical assay of all the three ingredients present in the formulation lies within prescribed limits i.e., 98.85% for Paracetamol, 95.44% for Caffeine and 98.48% for Chlorpheniramine Maleate. The dissolution profile of all the three ingredients lies outside the limits. Perusal of the method provided by the firm reveals that the method was incomplete. The product that does not comply the dissolution test is unable to produce therapeutic effectiveness. Such product cannot be registered whose method of analysis is faulty or incomplete, tn view of the foregoing facts, the Board unanimously decided to grant permission for prosecution against the following accused in the Drug Court:

i. M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar through its Managing Director Farjad Maqbool.

ii.	Farjad Maqbool	Managing Director
iii.	Arshad Ali	Production Incharge
iv.	Raza Khan	Quality Control Incharge
v.	Farhad Ali	Warrantor

of M/s Medicon Pharma (Pvt.) Ltd. 81/11 Industrial Estate Hayatabad, Peshawar. For the offences of:

a) Manufacturing for sale/Sale of Sub-standard drug

b) Issuance of false warranty

The Board further decided to recommend cancellation of registration of Tablet Medidol 500mg [Paracetamol: 500mg, Caffeine 65mg, Chlorpheniramine Maleate: 2mg] manufactured by M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial "Estate Hayatabad, Peshawar from Drug Regulatory ' Authority of Pakistan (DRAP) for provision of incomplete method of analysis.

Decision of 293rd meeting of Registration Board.

Registration Board deliberated that PQCB has already prosecuted responsible persons in Drug Court and also recommending DRAP for cancellation of registration. The Board decided to seek opinion of Legal Affair Division regarding issuance of show cause notice or otherwise.

Current Status of the Case.

In order to comply the above said decision of the Registration Board, The case file was forwarded to the Legal Affair Division for seeking opinion regarding the issuance of show cause notice or otherwise and the reply of the Legal Affair Division is reproduced as under;

"*That the PQCB granted permission for prosecution against the accused persons mentioned in para 8/N and also recommended to DRAP for cancellation of registration of subject product. The Registration Board deferred the matter for opinion of this Division for issuance of show cause notice or otherwise. In view of the above facts, the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.*"

Proceeding and Decision of 295th Meeting of Registration Board.

Registration Board considered the facts of the case and views comments of the Legal Affairs Division, DRAP, Islamabad that the Registration Board may issue the show cause notice under rule 24(17) of

Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board decided to defer the case for further deliberations in the next meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 21: CASE REFERRED BY PQCB, PUNJAB REGARDING KAYMAX 75MG SUGAR COATED TABLETS, B# GX1733, MANUFACTURED BY M/S QUAPER (PVT.) LT., 26-A S.I.E LAHORE ROAD, SARGODHA.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-325/2018 dated 17-09-2019 has informed that Provincial Inspector of Drugs Tehsil Jampur Rojhaan, district Rajanpur reported that:

i. He, on 26-06-2018, inspected the business premises of M/S Saleem Medical Store at Bangla Hidayat Tehsil Rojhan District Rajanpur and took samples of two different types of drug on Form No. 04 for the purpose of test and analysis.

ii. One out of these drug samples, after test/ analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory Multan as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Sugar Coated Tablet. Kaymax 75mg (Diclofenac Potassium 75mg)	GX1733	M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan.	TRA No.01-56001323/DTL dated: 18-08-2018	**Analysis with Specifications:** Manufacturer's Specification **Disintegration Test:** Determined **18 out of 18 tablets were not disintegrated in specified time** Limit All the tablets should disintegrate within 30min **Does not comply).** Assay: Percentage 97.42% Limit 90-110% Result: The above sample is **Substandard** on the basis of test performed.

iii. M/S Saleem Medical Store at Bangla Hidayat Tehsil Rojhan District Rajanpur provided invoice/ warranty No.025644 dated 05-06-2018 issued by M/S Public Medical Store Whole Sale Chemist Muslim Bazar Kashmore who in turn provided invoice/warranty no.7640 dated 24-04- 2018 issued by M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan as a proof of its purchase.

iv. Warrantor portion was sent to M/S Public Medical Store Whole Sale Chemist Muslim Bazar Kashmore.

v. A copy of test report was sent to M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan with directions to explain their position and provide requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested to re-test the above- mentioned drug sample from Appellate laboratory NIH, Islamabad.

vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the same was declared as **Sub-standard,** as detailed below: -

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results	
Kaymax Tablets 75mg	GX1733	M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan	057-P/2019-dated: 09-04-2019	**Specifications Applied** USP-39 **Dissolution Test:**	
				Determined	**59.73% of the label amount. Five tablets out of six deviated from the limits (Q)**
				Limit	Not less than 75% (Q) of the label amount
				Does not comply with USP-39 **Result:** The sample is **Sub-standard** quality on the basis of tests performed.	

viii. A copy of NIH Test Report was sent to M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan with directions to provide the requisite information and to explain their position in this regard.

Drug Inspector requested for grant of permission for prosecution against the above- mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing/stocking /selling of Substandard Drug**
b. **Issuance of false warranty**

Show cause/personal hearing notice(s) issued to accused person(s)

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

- *M/S Quaper (Pvt.) Ltd stated that our firm is one of the leading and trusted national company, best known for its high-quality products, which are fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ cGMP guidelines is the hallmark of the company to meet the high expectations of the patients as well as Health care providers.*
- *That retained sample of the same batch no. kept under prescribed conditions was tested at our well-equipped QC Lab, which fully complied with approved specifications and was found of standard quality.*
- *That we neither received any warrantors portion of the sample nor manufacturer portion despite the lapse of three months which was required to be required to be received within statutory period of one week.*
- *The storage conditions of the medical store where sample was drawn, not mentioned by the drug inspector.*
- *Our product is sugar coated tablet, the limits defined by the British Pharmacopoeia for disintegration time for sugar coated is not more than 60minutes, but DTL erroneously applied specifications of the film coated tablets which is not justified.*

PROCEEDINGS & DECISION BY THE BOARD:

PQCB 208th meeting held on 27-06-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 208th meeting held on 27-06-2019. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons. No one appeared before the Board on behalf of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan. Secretary PQCB apprised the Board that request for adjournment was received from the firm. The Board after discussion decided to adjourn the case in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Personal hearing notice(s) issued to accused person(s)
Case is placed before the Board or further necessary action

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **210th meeting** held on **17-09-2019.** Mr Sadiq Hussain Secretary DQCB District Rajanpur & Mr Muhammad Kaleem Bhutta Drug Inspector Tehsil Jampur Rojhan were present. Drug Inspector briefed the Board about the facts of the case and requested for permission of prosecution. Accused Person Muhammad Saleem (Quality Control Manager) appeared before the Board on the behalf of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistanand submitted that;

a) Quaper Pharmaceutical industry is one of the leading and trusted national Pharmaceutical company, best known by its high-quality products, which are fully compliant with the Drugs Act 1976 and rules framed there under.

b) The storage condition of the medical store from where sample was drawn, not mentioned by the drug inspector.

c) Our sample was sent to NIH Islamabad by this honorable Board but NIH report tested our product applying USP method instead of BP and declared our product Substandard on physical basis for not complying with Dissolution test which was unwarranted and defective report as the whole test was performed without Pancreatic Enzyme without any legal justification which made the whole report doubtful.

d) Both DTL and NIH are contradictory and highly doubtful and benefit of doubt always goes to the accused.

e) He also mentioned that we have recalled all the stock from our distributors as good will gesture and we have also given the public notice through newspaper. So, He requested for the linnet view.

The Board after comprehensive perusal of the records and statements of the representatives of the firm observed that as the monograph of the subject drug product is not mentioned in BP. The label claim is false and the product is misleading in addition to substandard as declared by DTL & NIH, Islamabad. Moreover, the firm provided Manufacturer specifications to DTL Multan and it was declared as substandard based on disintegration test. On request of the firm the sample was sent to NIH, Islamabad for retesting and NIH, Islamabad has declared it substandard based on Dissolution test as it is the mistake on the part of the firm that label claim does not mention that the product is gelatinized sugar coated tablet so NIH, Islamabad applied USP-39 as the notification vide No. F-3-2/2006 DATED 05-06-2006 that stated that *"All the firms shall adopt the specifications mentioned in the official pharmacopoeias for all the formulations except those drugs not included in the official pharmacopoeia. For these drugs manufacturers may adopt their own specifications till the inclusion of that formulation in the official pharmacopoeias. After this decision firms will not be allowed to adopt their own specifications for the drugs, which are included in any of the official pharmacopoeias"* Furthermore honorable members rebutted firm arguments that due to unavailability of monograph in B.P, NIH Islamabad apply U.S.P Specifications. The Board further observed that dissolution is not a minor parameter in the drug testing. There is a linear relationship between bioavailability and dissolution rate of the drug product. Hence, the drug having low dissolution will have lower bioavailability and will be unable to reach up to the therapeutic concentration and therefore, will lead to therapeutic failure and may cause development of resistance as 'well. Keeping in view the foregoing facts, the Board unanimously decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. M/S Quaper (Pvt.) Ltd., 26-A S.I.E Lahore Road Sargodha, Pakistanthrough its Managing Director Muhammad Iftikhar.
2. Muhammad Iftikhar — Managing Director.
3. Fozia Naheed — Production manager/Warrantor.
4. Muhammad Saleem — Quality Control Manager.

Of **M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan** for the offences of:

a). Manufacturing/stocking /selling of Substandard Drug.

b.) Issuance of false warranty.

The Board after due deliberation and discussion at length, decided to send a letter to Registration Board to review the registration documents of the products of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 22: CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION SULFAPRIME, BATCH NO. I-109, MANUFACTURED BY M/S ATTABAK PHARMA ISLAMANBAD.

TheSecretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-331/2019 dated 14-12-2019 has informed that Provincial Inspector of Drugs Tehsil & District Sahiwal reported that:

i. She, on 13-07-2019 inspected the premises of Medicine Store of office of Directorate Live Stock, Jogi Chowk, Sahiwal and took samples of four different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these drug samples after test/analysis, was declared **Substandard and Misbranded by** Government Analyst Drug Testing Laboratory, Bahawalpur as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Injection Sulfaprime [(Trimethoprm 80mg Sulfadiazine 400mg)/ml 50ml]	1-109	M/s Attabak Pharmaceutical Industries. 5-C. 1-10/3 Industrial Area, Islamabad	TRA No 01-25004258/DTL dated:28-08- 2019	**Analysis with specifications applied:** MS/BP 2018 **Description (MS):** Suspension of almost white solid in pale straw solution filled in sealed amber glass vial (stated volume: 50ml) The label of the product does not bear the name of pharmacopoeia or document according to which product is manufactured (**The product is misbranded).** **Volume (BP) :** Limit: Not less than nominal (50ml) Determined: 50mL **pH (BP):** Limit: 10.0-10.5 Determined: **11.313 (Does not comply)Sterility (BP):** The product is sterile. **Assay (MS):** (Trimethoprim) Percentage: 100.72% Limit: 90-110% (Sulfadiazine) Percentage 98.65% Limit: 90-110% **Result:** The sample is **Substandard** on the basis of pH test and **Misbranded** as defined under clause (vi) of sub-section (s) of section 3 of the Drugs Act 1976.

iii. Store keeper, office of Directorate Live Stock, Jogi Chowk, Sahiwal provided invoice/ warranty No. DG-LS-SWL_0005-14-06-2019 dated 14-06-2019 issued by M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad as a proof of its purchase of the said drug, whereas the Drug Inspector accepted the above mentioned bill/warranty.

iv. Whereas, warrantor portion and a copy of test report of the drug sample was sent to M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad with directions to provide the requisite information and to explain their position in this regard.

Drug Inspector requested to grant permission for prosecution against the accused persons nominated

in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended) /DRAP Act, 2012 and Rules framed there under by the way of -

i. **Manufacturing/ Selling/ Stocking of Substandard/Misbranded drug**
ii. **Issuance of false warranty**

Show-cause notice(s) were issued to accused person(s).

Reply of The Firm to Showcause Notice:

M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad submitted that:

> *'That the product injection Sulfaprime have manufacturer specification and the PH determined by the DTL Bahawalpur are as per manufacturer specification.*
> *That the PH limit of injection Sulfaprime Is 10— 13 and the PH determined i.e. 11.3 is within limits which are as per manufacturers' specification.*
> *That the chemical assay of both the actives Trimethoprime and Sulphadiazine is with the limits.*
> *That same product injection Sulfaprime is supplied to Gujranwala which is analyzed from DTL Multan and the DTL Multan follow our manufacturers specification and the PH determined by DTL Multan is 11.73 which is as per manufacturers specification.*
> *That how it is possible that on some component of analysis of the same product i.e. Description and Assay manufacturers specification is applied while on some components of analysis i.e. sterility and pH, BP is applied.*
> *That the matter regarding the misbranded of the product we rectify the labels of the said product and* a *label and an affidavit is already submitted to PQCB Lahore Letter No PQCB/P- 1012-09/19 "*

Personal hearing notice(s) were issued to accused person(s).

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **215th meeting** held on **14-12-2019.** Ms. Roquia Parveen, Secretary DQCB Sahiwal and Ms. Sadaf Drug Inspector Tehsil & District Sahiwal were present along with original record of the case. Among accused persons, Sajid Hussain (Quality Control Manager) of M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad was present and submitted that the Government Analyst wrongly applied BP specifications (pH range=10.0-10.5) for pH determination instead of applying manufacturer's specifications (pH range=10-13) and declared the subject drug sample substandard. Thus, he disagreed with the DTL results and requested for lenient view based on application of wrong specifications.

In reply to a query from a Board member, representative of the firm stated that the subject drug sample got registered in 2009, since then they are producing this product according to firm's in-house specifications with pH range 10-13.

The Board, after careful scrutiny of the DTL report and statements of firm representative, observed that the subject drug sample has been declared substandard by the Government Analyst Drug Testing Laboratory on the basis of pH. The determined value of pH (11.313) is greater than the upper permissible limit i.e., **10.0-10.5** as given in British Pharmacopoeia. The Board was of the opinion that injecting more alkaline solutions (above the upper permissible limit of pH) may lead to discomfort, erythema and oedema at the site of injection. The Board further observed that the firm is continuously producing subject drug sample with more alkaline/out of range pH according to their own set, unjustified pH range.

Keeping in view the facts of the case, the Board after due deliberation and discussion, **unanimously** decided **to** grant **permission for prosecution** against the following accused persons in **Drug Court:**

1. **M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad** through its Managing Director Dr. Israr Hussain Shah
2. Dr. Israr Hussain Shah — Managing Director/Warrantor
3. Shaid Ahmad Yousafzai — Production Incharge
4. Sajid Hussain — Quality Control Manager

of M/s Attabak Pharmaceutical Industries, 5-C. 1-10/3 Industrial Area. Islamabad., for the offences of:

a) Manufacturing/ Selling/ Stocking of Substandard/Misbranded drug

b) Issuance of false warranty

The Board further decided to direct office of secretary PQCB to report to DRAP, thematter of unexplained and unjustified pH range specifications being used by the firm without performing any product development or stability studies.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 23: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 346, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-327/2018 dated 15-11-2019 wherein he has informed that Provincial Inspector of Drugs Tehsil Depalpur, District Okara reported that:

i. He on 04-01-2018 inspected the business premises of M/S Macca Medical Store, Kasur Road Rajowal Depalpur, District Okara and took samples of three different types of drugs on form No 4 for the purpose of test/analysis.

ii. Out of which one drug sample after test/analysis was declared **Substandard** by the Government Analyst Drug Testing Laboratory Punjab, Bahawalpur as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tabs. Dologin [Mefenamic acid; 250mg]	346	M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan	TRA No: 01-01010653/DTL Dated: 21.03.2018	**Analysis with specifications applied:** Manufacturer's Specifications **Composition:** Each dispersible tablet contains: Mefenamic acid ..... 250mg **Description:** A white colored tablet, oblong in shape, bisected on one side and plain on other side. Packed in blister packing of 10 units. **Disintegration:** Eight tablets out of eighteen were not disintegrated within specified time, i.e. 3 minutes. **Limit: 16 tablets out of 18 must be disintegrated within specified time, i.e. not more than 3 minutes** **(Does not comply specifications)** **Identification:** Mefenamic acid is identified. **Assav: (Mefenamic acid)** Stated:……250mg Determined: ……..253.365mg Percentage: ……101.346% Limit:……..95-105 % **Result:** The sample is Substandard on the basis of test performed.

iii. M/S Macca Medical Store Kasur Road Rajowal Depalpur, District Okara provided invoice/warranty No.19853(A) dated 16-10-2017 issued by M/S Asif Trading Corporation, 45 Akbar Road Okara who in turn provided invoice/warranty No. PH-88085 dated 18-09-2017 issued by M/S Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi-Pakistan as a proof of its purchase of the said drug, whereas the Drug inspector accepted the above-mentioned bill/warranty.

iv. Whereas, warrantor portion and a copy of test report was sent to M/S Asif Trading Corporation, 45 Akbar Road Okara.

v. Whereas, a copy of test report of drug sample was sent to M/S Opal Laboratories (Pvt.) Ltd., LC- 41, L.I.T.E., Landhi, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard.

REPLY OF THE FIRM TO DRUG INSPECTOR:

M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan submitted that:

"portion of sealed sample was received on 03-04-2018 after passage of 89 days, although according to law it should have been dispatched within 7 days. Moreover, we had thoroughly checked, upon detail evaluation both warrantor sample and reference sample, found OK and meets specification It is worth noting that we have not been asked for testing method and other required relevant detail for Quality Control laboratory testing. "

Drug Inspector requested for grant of permission for prosecution against the accused persons involved in the subject case who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. Manufacturing for sale/Sale of Substandard drug.
b. Issuance of false warranty.

Showcause/personal hearing notice(s) was issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

209th meeting held on 17-07-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of The Drugs Act, 1976 in its 209th meeting held on 17-07-2019 Mr. Zaheer-udin Babar Secretary DQCB Okara and Mr. M Irfan Munir Drug Inspector Tehsil Depalpur & District Okara were present. Drug Inspector briefed the Board about facts of the case and requested to grant permission for prosecution against the accused persons. Secretary PQCB apprised the Board that showcause/personal hearing notice was duly served to the accused persons. Counsels of the firm, Sarnia Khalid (Advocate) and M. Zohaib Shahid (Advocate) were present on behalf of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan and submitted written request for adjournment of the subject case.

The Board after due deliberation and discussion decided to **adjourn** the case in the best interest of justice and provide another but final opportunity of personal hearing to the accused persons

Personal hearing notice(s) issued to accused person(s).

211th meeting held on 30-09-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act. 1976 in its **211th**meeting held on 30-09-2019. Mr. Zaheer-udin Babar Secretary DQCB Okara was present along with the original case record. Secretary DQCB Okara briefed the Board about facts of the case and requested to grant permission for prosecution against the accused persons. Secretary PQCB apprised the Board that personal hearing notice was duly served to the accused persons. Counsel of the firm, M. Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan and submitted that a similar case of Tablet Dologin [Mefenamic Acid: 250mg] with batch no. 348 was previously considered by the Board. The DTL report of both these cases declared Tablet Dologin [Mefenamic Acid: 250mg] substandard on the basis of Disintegration test. He further stated that inspection of Batch manufacturing record was recommended in the other case and requested that the subject case may be clubbed with case of Tablet Dologin [Mefenamic Acid: 250mg] with batch no. 348

The Board after detailed scrutiny of the record and in light of the arguments raised by the

Counsel of the firm observed that a case of Tablet Dologin [Mefenamic Acid: 250mg] Batch no. 348 with R. no. 36/2018 was considered by the Board in its 207th meeting held on 13-06-2019. The Board further observed that there are similarities in these two cases as both the batches (batch no. 348 & 349) were manufactured in similar time period and they failed on same grounds i.e . Disintegration test. The inspection of Batch manufacturing record was conducted on 23rd September 2019 by the nominated team and the final report is still awaited.

The Board after due deliberation and discussion, unanimously decided to accept therequest of the counsel of the firm and directed the office of Secretary PQCB to club the case of Tablet Dologin [Mefenamic Acid. 250mg] Batch no 346 with the other case of Tablet Dologin [Mefenamic Acid 250mg] Batch no 348 of R. no. 36/2018 for further consideration by the Board

INSPECTION REPORT OF M/S OPAL LABORATORIES (PVT.) LTD, LC-41, L.I.T.E., LANDHI, KARACHI.

Panel Members:

Dr. Prof(R) Mahmood Ahmad, Member, PQCB.
Dr. Muhammad Munawar Hayat CDC Punjab
Date of Inspection: 23-09-2019.

Detail of matter and Firm:

- *The management of the firm is changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017.*
- *QA of Firm generated request for change the art work of label on 15-01-2018*
- *Tablet Dologin (Mefenamic acid) 250mg. Batch No. 348 was manufactured on 09/2017*
- *The said drug was declared substandard on basis of Disintegration test by DTL Rawalpindi on 07-05-2018.*

OBSERVATIONS:

a) *The firm is manufacturing "**dispersible"** tablets but having the registration of plain tablets.*
b) *Product Specification of Tablet Dologin is B.P.as mentioned in method and assay is by titration.*
c) *At time of inspection, the production manager of firm informed that firm is now manufacturing the plain dologin tablets from last one year.*
d) *Currently, the firm is using the same formulation as before without any variation.*
e) *API Mefenamic acid is of BP specification.*
f) *On 18/08/2018 firm destroyed the remaining packing material /label bearing dispersible word through Gel Pvt. Ltd.*

Batch Processing Record of specific product:

01. *BMR Record: available.*
02. *QC retain sample: Not available Expired.*
03. *Testing method: available*
04. *Manufacturing started on 29/09/2017 and completed on 09/10/2017.*

Manufacturing Process of tablet Dologin 250mg:

1. *The firm provided the record of process of manufacturing of tablets Dologin, the firm has no reference of dispersible tables of Mefenamic acid of any other firm in the world.*
2. *The firm developed the method of manufacturing of tablet Dologin by using the one disintegrant at 5% percentage only in final blending and found Primogel (Sodium starch glycolate) as suitable for manufacturing of dispersible Dologin tablets.*

Conclusion:

The panel is of the opinion that:

01. This defect in tablet is due to improper development of dispersible tablet formulation and the firm has not performed any in-vitro tests or study to evaluate the status of dispersible formulation.
***02.** The Firm has given self-life of 3 years to Plain tablets whereas 2 years of shelf-life has been given to dologin DS tablets.*
03. The firm is performing only Disintegration test and not performing dissolution test.
04. The firm has not recalled the drug from the market which is still not expired. The expiry of the drug is 08/2020.
*05. The firm is manufacturing **"dispersible"** tablets illegally while they have the registration of plain tablets.*
***06.** The firm is advised to redesign its formulation to differentiate between plain and dispersible Tablet and stop manufacturing of dispersible tablets.*
Submitted for final decision to Board

Personal hearing notice(s) issued to accused person(s).

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Inspection report was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **213th** meeting held on 15-11-2019. Ms. Barkhoona Waheed Secretary DQCB Jhelum was present along with original record of the case. Counsel of the firm, M Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi and submitted that the statement mentioned on the DTL report that "no monograph of

Mefenamic acid dispersible tablet is available in official monographs" as dispersible tablets monograph is available in European Pharmacopeia. He further submitted that Mefenamic acid is commonly used to treat mild to moderate pain and its repeated use can cause serious gastrointestinal toxicity, thus, the clinical justification for manufacturing of dispersible Dologin Tablet is to avoid these adverse effects.

Dr. Munawar Hayat, Chief Drugs Controller, Punjab apprised the Board about the observations made by the inspection team during the visit of the firm. In the light of the facts stated in the inspection report, the Board observed that

- The firm has registration of plain tablets of Mefenamic acid but it was manufacturing dispersible tablet which is illegal. Moreover, the firm is manufacturing Mefenamic acid dispersible tablets, the reference of which is neither available in any pharmacopeia nor such reference is available for its manufacturing by any firm in the world.
- The defect in the tablet was due to improper development of dispersible tablet formulation and that the firm has not performed any in-vitro tests or study to evaluate the stability of dispersible formulation.
- The firm was performing only Disintegration test and not performing dissolution test while according to official pharmacopoeia, both tests are necessary to be performed.
    - The expiry date of the subject drug is 08/2020 but the firm has still not recalled it from the market.
- According to the letter from DRAP to M/S Opal Laboratories LC-41, L.I.T.E., Landhi. Karachi, the management of the firm was changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017. However, in PQCB 194th meeting dated 18-10-2018, the current CEO of the firm appeared before the Board and stated that the firm has been acquired by the new management in June 2017. The subject drug was manufactured in September 2017 i.e. after the new management acquired the firm. Moreover, no sale deed has been provided by the firm about handing/taking over of the firm, in support of the claim that on such date they were having the responsibility of this offense or not. Further, in writ petition no 24146/2019, as reflected by the orders of Ayesha A. Malik J dated 16-05-2019 the petitioner has not taken any such stance rather he was in the proper defense of case in the High Court in said writ petition.

Keeping in view the foregoing facts, the Board unanimously decided to grant permission for Prosecution against the following accused persons in the Drug Court

01. M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan through its Chief Executive Officer Dr. Ali Afzal
02. Dr. Ali Afzal Chief Executive Officer
03. Jhanzaib Akram Managing Director
04. Rozina Babar Quality Control Manager/Warrantor
05. Ikram Zubairi Production Manager

of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan for the offences of:

a. Manufacturing for sale/Sale of Substandard drug.
b. Issuance of false warranty.

The Board further decided to recommend the Registration Board, Drug Regulatory Authority of Pakistan for cancellation of registration of Tablet Dologin (Mafenamic acid) 250mg manufactured by M/S Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already

prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 24: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 348, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-36/2018 dated 15-11-2019 has informed that Provincial Inspector of Drugs Tehsil Jhelum reported that:

v. He on 27-02-2018 inspected the business premises of M/S M/s Tariq Pharmacy, Amin market, Muhammadi chowk, Tehsil Jhelum and took sample of two different type of drugs on Form No. 04 - for the purpose of test and analysis.

vi. One of drug sample after test/ analysis, was declared **Substandard** by Government analyst Drug Testing Laboratory Rawalpindi as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. &	DTL Test Report Results
Tabs. Dologin [Mefenamic acid; 250mg]	348	M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan	TRA No: 01-13000725/DTL Dated: 07-05-2018	Physical Description White to off white colored, oblong shaped tablet, bisect line on both sides, packed in Alu-PVC blister (1x10) Average Weight Result 385.82mg Limit 370.409.5mg Disintegration Test: Stage 1 4 out of 6 units fail to comply the disintegration test. Stage 2 10 out of 18 units fail to comply the disintegration test. **(Does not comply)** If 1 or 2 dosage units fails to disintegrate, repeat the test on 12 additional units, the requirements of the test are met if not less than 16 units tested have disintegrated. Limit NMT 3 min Identification; Mefenamic Acid identified Assay: Stated: 250mg/Tablet Determined: 253.88mg/Tablet Percentage: 101.553% Limit: 95-105% Result: Sample is Substandard on the basis of disintegration test.

iii. M/s Tariq Pharmacy, Jhelum provided invoice/warranty No.PH-88716, dated 13-10-2017 issued by M/S Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi-Pakistan as the proof of their purchase.

iv. Copy of test/analysis report and warrantor portion was sent to warrantor M/s Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi with the direction to explain their position and provide requisite information in this regard.

v. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

(Accused No. 1)

a. Stocking/Selling of Substandard drug

(Accused No. 2-5)

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

Show-cause/Personal hearing notice(s) issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Qua ty Control Board, under section 11 of the Drugs Act 1976 in its **194th meeting held on 18-10-2018.** Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons Accused Muhammad

Qasim (Proprietor) of M/s Tariq Pharmacy, Amin market, Jhelum stated that he purchased the drug directly from manufacturer M/s Opal Pharma and submitted the copy of bill/warranty to the office of Drug Inspector within seven days. Chief Executive Officer of M/s Opal Pharma that the firm was acquired by the new management in June 2017. The said Batch of the drug was manufactured by old management; hence they are not responsible for commission of the offence. In response of a query, QC manager of the firm replied she has been working with the firm since 2016 and the product is being manufactured under B.P specifications. She added that the said drug is registered as a plain tablet not as a dispersible tablet and she raised this issue before the management with the request rectify the label claim. CEO of the firm apprised the Board that in response to the intimation by the QCM the firm has stopped manufacturing of the said drug as dispersible tablet. QC retained portion was tested and its disintegration time was found within required limits. He requested to drop the case. The Board, after detailed scrutiny of the record, due deliberation and detailed discussion observed that no monograph of Mefenamic acid dispersible tablet is available in official pharmacopoeias. The product was not registered as a dispersible tablet by the **MOH/DRAP.** The said batch of drug was manufactured in September 2017 after acquisition of the firm by the new management. Hence, new management is responsible for manufacturing of the substandard drug in a dosage form not approved by the regulatory authority. In the view of foregoing facts the Board, decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of:

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

The Board further decided to drop the proceedings against the accused Muhammad Qasim (Proprietor) of M/s Tariq Pharmacy, Amin market, Muhammadi chowk, Tehsil Jhelum.

Review Petition:

The firm has filed the Review Petition against the orders of Provincial QualityControl Board of even No. dated 05-11-2018:

Dr. Ali Afzal Presently CEO of M/s Opal Laboratories (Pvt.) Ltd., LITE, Landhi, Karachi

Verses

Provincial Drug Inspector, Tehsil Jhelum, Jhelum,

A. That at the time of sampling of the product in question by the Respondent, the Petitioner was not Chief Executive officer of the company the rather Mr Tariq Ikram was the Chief Executive Officer/ Managing Director of the company at that time of manufacturing of the Product in question and the same is evident from the letter dated 19-12-2018 issued by the Central Licensing Board of the DRAP whereby the change of management of the company taken place. As per Section 34 of the Drugs Act, 1976 only those directors may be held responsible within whose knowledge the alleged offence was committed. Had the complainant drug inspector carried out any investigation in the matter or reflected upon status of the Petitioner in the management of the company, he would have certainly excluded his name from the list of accused persons. Therefore, the Petitioner cannot be held liable for the commission of alleged offences and name of the Petitioner as the CEO of the company is liable to be dropped from the instant case

B. That the Petitioner has been charged under section 23 and under 27(4) of the Drugs Act, 1976 in ignorance of the provisions of Section 32 of the Drugs Act which provides that the person not being the manufacturer of the drug in question cannot be held liable for non-fulfillment of responsibility of the manufacturer. He just has to satisfy himself generally to the extent that the drug did not violate the provisions of the act

C. That without prejudice to the above the test report of the DTL Rawalpindi is for various reasons completely in effective, invalid and unfit for the purpose of evaluation of the quality and standard of the drug, either under the law and under the facts, and the same are of no consequence or

merit for declaring the Tablet Dologin (Mefenamic Acid) 250 mg as sub-standard.

D That this honorable Board has committed material irregularity while passing the impugned order though giving its observation that "no monograph of Mefenamic acid dispersible tablet is available in official pharmacopeias" it is submitted that this observation is totally wrong as official monograph of dispersible tablet is available. As per 'Ph Eur. monograph 0478' several categories of tablets for oral use are provided which may be distinguished as follows:

i. Uncoated tablets;
ii. Coated tablets;
iii. Effervescent tablets:
iv. Soluble tablets;
v. Dispersible tablets
vi. Orodispersible tablets;
vii. Gastro-resistant tablets;
viii. Modified release tablets
ix. Ablets for use in mouth:
x. Oral lyophilisates;

E. It is clarified that the Dologin Tablet was developed as buffered and dispersible effects, however, it was not mentioned in the brand name, in this regard, a letter dated 24-01-2004 for price revision of the product was sent to the Ministry of Health wherein it was mentioned that the Product is Buffered' and 'Dispersible' to overcome the side effects of GIT. Therefore, this observation by this Honorable Board is wrong that 'the Product was not registered as a dispersible tablet by the MOH/ DRAP'.

F. The clinical justification of the dispersible Dologin Tablets of 'Mefenamic acid' is widely used in the treatment of mild to moderate pain including headache, dental pain, post-operative/ postpartum pain, dysmenorrhea, rheumatic disorders such as osteoarthritis and rheumatoid arthritis. The chemistry and pharmacology of Mefenamic acid is no more hidden from the eyes of the prescribers besides the fact that its usage cause serious gastrointestinal toxicity such as bleeding, ulceration and perforation any time without any warning. The common adverse effects of Mefenamic acid are gastrointestinal disturbances, peptic ulceration and gastrointestinal bleeding The Petitioner/ Opal Laboratories under took studies to eliminate or reduce the above- mentioned side effects of Mefenamic acid during its usage in their Research and Development department. The first idea was to coat the tablet with an acid resistant material but it was dropped, as it will delay the onset action of the drug for almost two hours. During the further studies and review of the published literature another theory was developed that if the drug is made buffered and dispersible, the side effects can be eliminated or at least be minimized. The advantage of buffered Mefenamic Acid is to be antagonize the acidity of stomach to prevent further decrease of pH and hence minimize the serious adverse effects of Mefenamic acid on one hand and on the other hand increases absorption due to lesser acidic environment created in the stomach. Due to the dispersible action the drug is rapidly dispersed throughout the lumen of the gastrointestinal tract and as a result each particle proves its own absorption of Mefenamic acid. The theoretical results were testified at R & D with practical, the approval was received to launch the product with the slogan of buffered Dispersible Mefenamic Acid tablets. As this new idea of dispersion and buffering reached the prescribers the more and more patients were put onto Dologin tablets with buffered and dispersible action and today many are convinced remaining few to touch for their acceptance.

G. That be that as it may and without prejudice to the foregoing, and the legality of the decision of the previous management to add the word 'dispersible' on the label, the new management after taking over the company in Dec 2017 has removed the word 'dispersible' from the label.

H. That without prejudice to the foregoing, the Government Analyst has failed to mention complete protocols of the test applied in the DTL report. It is a trite law that without protocols of the test report is inconclusive and cannot be used as evidence against the accused persons. The Impugned report is liable to be set aside being based on incomplete report.

I. That the petitioner carried out a thorough check on retained samples of Tablet Dologin

(Mefenamic acid) 250mg Batch no. 348 and has made similar tests on random samples of the same, no such abnormality was found, the product is well within the limit and is of standard quality. All parameters of test and analysis are within acceptable limits.

J. That Sections 11 (5)(b) and 19(6) of the Act read with Rule 5(3) of the Punjab Drug Rules. 2007 cast a duty upon the Respondent and this honorable Board to take every action under the Impugned reports by applying conscious mind and not in a mechanical manner It is regretted that the impugned Order has been passed in violation of Section 11 (5)(b) and 19(6) of the Drugs Act and Rule 5(3) of the Punjab Drug Rules. 2007.

K. That it is the duty and obligation of the public functionaries to act justly fairly, equitably, reasonably without any element of discrimination and squarely within the parameters of law as is envisaged by Article 4 of the Constitution.

L. That in addition to above, the Petitioner reserved his right to submit further assistance to this honorable Board during the arguments of the instant petition.

Prayer:

In view of the foregoing, it is most respectfully and humbly submitted that this honorable Board may be pleased to:

x. Accept the instant review petition, delete the name of the Petitioner from the list of accused persons in the case no. PQCB/R-36/2018;

xi. Set aside the Impugned Order dated 05-11-2018 being passed without proper examination of available record;

xii. Suspend the Impugned Order till the decision of the instant review petition

Any other relief which this Honorable Forum deems fit and appropriate in the circumstance of the case may also be allowed.

Review petition:

The following accused have filed the Review Petition against the orders of
Provincial Quality Control Board of even No. dated 05-11-2018:

1. M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi through its authorized officer Ms. Rozina Babar
2. Ms. Rozina Baber d/o Ibarat-ullah- Baber Quality Control Manager/ warrantor of M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi.
3. Mr. Ikram Zubairi Production Manager of M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi.

Verses

Provincial Drug Inspector, Tehsil Jhelum, Jhelum.

A That the test report of the DTL Rawalpindi consists of technical defects and therefore ineffective for the purpose of evaluation of the quality and standard of the drug, either under the law or under the facts, and the same are of no consequence or merit for declaring the Tablet Dologin (Mefenamic Acid) 250mg as sub-standard.

B. That this honorable Board has committed material irregularity while passing the impugned order though giving its observation that "no monograph of Mefenamic acid dispersible tablet is available in official pharmacopeias". It is submitted that this observation is totally wrong as official monograph of dispersible tablet is available. As per 'Ph Eur monograph 0478' several categories of tablets for oral use are provided which may be distinguished as follows;

i. Uncoated tablets;
ii. Coated tablets;
iii. Effervescent tablets;
iv. Soluble tablets;
v. Dispersible tablets:
vi. Orodispersible tablets;
vii. Gastro-resistant tablets;
viii. Modified-released tablets:
ix. Tablets for use in the mouth;

x. Oral lyophilisates.

C. It is clarified that the Dologin Tablet was developed as buffered and dispersible effects, however, it was not mentioned in the brand name, in this regard, a letter dated 24-01-2004 for price revision of the product was sent to the Ministry of Health wherein it was mentioned that the Product is Buffered' and 'Dispersible' to overcome the side effects of GIT Therefore, this observation by this Honorable Board is wrong that 'the Product was not registered as a dispersible tablet by the MOH/ DRAP'.

D. The clinical justification of the dispersible Dologin Tablets of 'Mefenamic acid' is widely used in the treatment of mild to moderate pain including headache, dental pain, post-operative/ postpartum pain, dysmenorrhea, rheumatic disorders such as osteoarthritis and rheumatoid arthritis. The chemistry and pharmacology of mefenamic acid is no more hidden from the eyes of the prescribers besides the fact that its usage cause serious gastrointestinal toxicity such as bleeding, ulceration and perforation any time without any warning The common adverse effects of mefenamic acid are gastrointestinal disturbances, peptic ulceration and gastrointestinal bleeding The Petitioner/ Opal Laboratories under took studies to eliminate or reduce the above- mentioned side effects of Mefenamic acid during its usage in their Research and Development Department. The first idea was to coat the tablet with an acid resistant material but it was dropped, as it will delay the onset action of the drug for almost two hours During the further studies and review of the published literature another theory was developed that if the drug is made buffered and dispersible, the side effects can be eliminated or at least be minimized. The advantage of buffered Mefenamic Acid is to be antagonize the acidity of stomach to prevent further decrease of pH and hence minimize the serious adverse effects of Mefenamic acid on one hand and on the other hand increases absorption due to lesser acidic environment created in the stomach. Due to the dispersible action the drug is rapidly dispersed throughout the lumen of the gastrointestinal tract and as a result each particle proves its own absorption of Mefenamic acid. The theoretical results were testified at R &D with practical, the approval was received to launch the product with the slogan of buffered Dispersible Mefenamic Acid tablets. As this new idea of dispersion and buffering reached the prescribers the more and more patients were put onto Dologin tablets with buffered and dispersible action and today many are convinced remaining few to touch for their acceptance.

E. That be that as it may and without prejudice to the foregoing, and the legality of the decision of the previous management to add the word 'dispersible' on the label, the new management after taking over the company in Dec 2017 has removed the word dispersible' from the label

F. That without prejudice to the foregoing, the Government Analyst has failed to mention complete protocols of the test applied in the DTL report. It is a trite law that without protocols of the test report is inconclusive and cannot be used as evidence against the accused persons. The Impugned report is liable to be set aside being based on incomplete report

G. That the petitioner carried out a thorough check on retained samples of Tablet Dologin (Mefenamic acid) 250mg Batch no. 348 and has made similar tests on random samples of the same, no such abnormality was found, the product is well within the limit and is of standard quality. All parameters of test and analysis are within acceptable limits.

H. That Sections 11 (5)(b) and 19(6) of the Act read with Rule 5(3) of the Punjab Drug Rules, 2007 casta duty upon the Respondent and this honorable Board to take every action under the Impugned reports by applying conscious mind and not in a mechanical manner It is regretted that the impugned Order has been passed in violation of Section 11 (5)(b) and 19(6) of the Drugs Act and Rule 5(3) of the Punjab Drug Rules, 2007.

I. That it is the duty and obligation of the public functionaries to act justly fairly, equitably, reasonably without any element of discrimination and squarely within the parameters of law as is envisaged by Article 4 of the Constitution.

J. That in addition to above, the Petitioner reserved his right to submit further assistance to this honorable Board during the arguments of the instant petition.

Prayer:

In view of the foregoing, it is most respectfully and humbly submitted that this honorable Board

may be pleased to:

i. Accept the instant review petition, delete the name of the Petitioner from the list of accused persons in the case no. PQCB/R-36/2018;

ii. Suspend the Impugned Order til! the decision of the instant review petition.

Any other relief which this Honorable Forum deems fit and appropriate in the circumstance of the case may also be allowed.

The Petitioners also requested for grant of interim relief till the final decision of the titled Review petition.

Personal hearing notice(s) issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

199th meeting held on 31-01-2019:

Subject Review Petition was considered by the Provincial Quality Control Board, undersection 11 of the Drugs Act 1976 in its 199lhmeeting held on 31-01-2019. Ms Barkhoona Waheed Secretary DQCB District Jhelum and Mr. Naseer Ahmed Drug Inspector Tehsil &District Jhelum were present Counsel of the firm Zohaib Shahid Lodhi (Advocate) appeared before the Board and submitted that the firm was unaware that this case is placed at the agenda of 199th meeting dated 31-01-2019. as they did not receive personal hearing notice. He agitated his grievances as mentioned in grounds of the review petition submitted by the firm.

The Board after detailed scrutiny of the record and grounds of the review petition submittedby the firm, due deliberation &discussion observed that the current CEO of the firm appeared before the Board in PQCB 194th meeting dated 18-10-2018 and gave the statement that the firm has been acquired by the new management in June 2017 and the subject drug was manufactured in September 2017 after acquisition of the firm by the new management. Government Analyst has tested the subject sample according to the Manufacturer's specifications as provided by the firm and the sample fails to comply with manufacturer's own specifications and the report of Government Analyst is the conclusive evidence of the facts stated therein.

In view of the foregoing facts, the Board unanimously decided to turn-down the subject review petition and uphold its previous decision taken in PQCB 194th meeting held on 18-10-2018 for grant of permission for Prosecution against the following accused in the Drug Court:

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of

- **a.** Manufacturing for sale/stocking/Selling of Substandard drug
- **b.** Issuance of false warranty

203rd meeting dated 29-03-2019:

Request of the firm to grant fair opportunity of hearing was placed as issue in 203rd meeting dated: 29-03-2019

Request from M/s Opal Laboratories (Pvt.) Ltd. has been received stating that:

1. We write to you on behalf of M/s Opal Laboratories (Pvt.) Ltd. (the "company", our "client").

2. Kindly refer to the previous letter dated 01-02-2019 whereby our client has made a request to your good office for granting of fair opportunity of hearing.

3 That we on the instructions of our Client filed a Review Petition before this honorable Board challenging the Order dated 05-11-2018 of the Provincial Quality Control Board, Punjab. The said Review Petition was lastly fixed for hearing before the honorable Provincial Quality Control Board, Punjab (the "Board") on 31-01-2019 m its 199'" meeting.

4. *That it is pertinent to mention here that no hearing notice for the aforesaid meeting was received by the Company till the date of hearing i.e. 31-01-2019. The associate of the undersigned counsel who was present in the office of the Board to attend hearing of other cases, informed the Company telephonically that their Review Petition is also fixed in the aforesaid hearing*

5. *Since, our Client is based in Karachi, it was impossible for the officials of the Company to*

reach and attend the hearing on a very short notice. Therefore, our Client gave us instructions to seek adjournment on ground of these unavoidable circumstances, which the honorable Board had flatly refused and directed the associate to plead the case knowing the fact that concerned accused persons and supporting documents were not available with him. However, the honorable Board in absence of the representative of the Company and without conducting a proper hearing of our Client has passed the Order dated 31-01-2019. whereby permission for prosecution has been granted to the Drug Inspector illegally, which is against the principles of natural justice, equity and fair play and also against the principle of Audi Alerm Partem'

6 Now. through the instant letter we hereby again request you to kindly provide a fair opportunity of hearing to the Company before taking any action against the Company and the accused persons in the titled case, so that we may properly assist the Board in this case.

7. *It is reiterated here that the absence of the Company and its officials in the meeting dated 31-01-2019 was neither intentional nor deliberate rather it was due to the circumstances mentioned in Para 2-4 of the instant Application. No adverse order could have been passed without hearing the stance of the Company.*

8. *We have a strong and good prima facie case in our favor and there is very likelihood of the case being dropped if the honorable Board may grant us a proper opportunity of hearing.*

9. *It in the interests of justice that stance of the Company may be heard in a proper hearing, therefore, it is requested to kindly consider the instant application and fix our review petition in upcoming meeting scheduled.*

PROCEEDINGS & DECISION BY THE BOARD:

Issue was considered by Provincial Quality Control Board under Section 11 of the Drugs Act 1976 inits 20rd meeting dated 29-03-2019. The Board observed that the review petition filed by the firm has already been upheld by the Board in its 199th meeting dated 31-01-2019 and there is no provision to give a chance of personal hearing after review petition, in view of the foregoing facts, the Board unanimously decided to turn-down the request of the firm.

Honourable High Court Judgment dated: 16-05-2019 in Writ Petition No. 24146/2019 Titled as "M/S Opal Laboratories (Pvt.) Vs Provincial Quality Control Board etc."

"The instant Petition is allowed, order dated 31-01-2019 issued by Respondent No.l is set aside. The review petition filed by the Petitioner shall be deemed pending before the respondent No.l (PQCB) who is directed to decide it afresh in accordance with law within six weeks' time of certified copy of this order."

Personal hearing notice(s) issued to accused person(s).

PROCEEDINGS & DECISION BY THE BOARD:

Subject Review Petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 207th meeting held on 13-06-2019. Ms. Barkhoona Waheed Secretary DQCB District Jhelum and Mr Naseer Ahmed Drug Inspector Tehsil & District Jhelum were present along with original case file. Counsel of the firm Miss Sarnia Khalid (Advocate) appeared before the Board and agitated his grievances as mentioned in grounds of the review petition submitted by the firm. She added that according to DTL report the product was tested on Manufacturer specifications but the firm was not asked to provide method of testing. Our product is plain tablet instead of dispersible tablet (which was mistakenly printed on the label of the product sampled), so disintegration time limit of plain tablet (i.e NMT15 min) should have been applied on the product. This incorrect printing of dosage form on the label of the product is an offence under Labelling and Packaging Rules and DTL Rawalpindi was supposed to declare it misbranded instead of substandard. She further added that at the time of manufacturing of the product in question, her client was not Chief Executive officer of the company rather Mr. Tariq Ikram was the Chief Executive Officer/ Managing Director of the company the same is evident from the letter dated 19-12-2018 issued by the Central Licensing Board of the DRAP whereby the change of management of the company is mentioned. As per Section 34 of the Drugs Act, 1976 only those directors are held responsible with whose knowledge the alleged offence is committed.

The Board after detailed scrutiny of the record, grounds of the review petition and verbal arguments submitted by the counsel of the firm, due deliberation &discussion observed that in order to dig out whether the product in question was manufactured under new administration/ ownership or not. the Batch manufacturing record of the product need to be evaluated. Therefore, the Board decided to constitute a committee comprising of the following members to visit **M/S Opal Laboratories LC-41, LITE, Landhi, Karachi** for record verification and submit report for consideration by the Board:

1. **Prof Dr. Mehmood Ahmad** Convenor
   (Member PQCB)
2. **Munawar Hayyat** Member
   Chief Drugs Controller Punjab /Member PQCB

INSPECTION REPORT OF M/S OPAL LABORATORIES (PVT.) LTD, LC-41, L.I.T.E., LANDHI. KARACHI.

Panel Members:

Dr. Prof(R). Mahmood Ahmad, Member, PQCB.

Dr. Muhammad Munawar Hayat CDC Punjab

Date of Inspection: 23-09-2019

Detail of matter and Firm:

The management of the firm is changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017.

- QA of Firm generated request for change the art work of label on 15-01-2018
- Tablet Dologin (Mefenamic acid) 250mg, Batch No. 348 was manufactured on 09/2017.
- The said drug was declared substandard on basis of Disintegration test by DTL Rawalpindi on 07- 05-2018

OBSERVATIONS:

1 The firm is manufacturing **"dispersible"** tablets but having the registration of plain tablets.

2 Product Specification of Tablet Dologin is B.P as mentioned in method and assay is by titration

3 At time of inspection, the production manager of firm informed that firm is now manufacturing the plain dologin tablets from last one years.

4. Currently, the firm is using the same formulation as before without any variation.
5. API Mefenamic acid is of BP specification.
6. On 18/08/2018, firm destroyed the remaining packing material /label bearing dispersible word through Gel Pvt. Ltd.

Batch Processing Record of specific product

1. BMR Record: available.
2. QC retain sample: Not available. Expired.
3. Testing method: available
4. Manufacturing started on 29/09/2017 and completed on 09/10/2017

Manufacturing Process of tablet Dologin 250mg:

1. The firm provided the record of process of manufacturing of tablets Dologin, the firm has no reference of dispersible tables of mefenamic acid of any other firm in the world.
2. The firm developed the method of manufacturing of tablet Dologin by using the one disintegrant at 5% percentage only in final blending and found Primogel (Sodium starch glycolate) as suitable for manufacturing of dispersible Dologin tablets.

Conclusion

The panel is of the opinion that:

1. This defect in tablet is due to improper development of dispersible tablet formulation and the firm has not performed any *in-vitro*tests or study to evaluate the status of dispersible formulation.
2. The Firm has given self-life of 3 years to Plain tablets whereas 2 years of shelf-life has been given to dologin DS tablets.
3. The firm is performing only Disintegration test and not performing dissolution test.

4. The firm has not recalled the drug from the market which is still not expired The expiry of the drug is 08/2020.

5 The firm is manufacturing **dispersible"** tablets illegally while they have the registration of plain tablets

6 The firm is advised to redesign its formulation to differentiate between plain and dispersible Tablet and stop manufacturing of dispersible tablets.

Submitted for final decision to Board.

Personal hearing notice(s) issued to accused person(s).

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Inspection report was considered by the Provincial Quality Control Board, under section 11of the Drugs Act 1976 in its **213th**meeting held on 15-11-2019. Ms. Barkhoona Waheed Secretary DQCB Jhelum was present along with original record of the case. Counsel of the firm, M. Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi and submitted that the statement mentioned on the DTL report that "no monograph of Mefenamic acid dispersible tablet is available in official monographs" as dispersible tablets monograph is available in European Pharmacopeia. He further submitted that mefenamic acid is commonly used to treat mild to moderate pain and its repeated use can cause serious gastrointestinal toxicity, thus, the clinical justification for manufacturing of dispersible Dologin Tablet is to avoid these adverse effects.

Dr. Munawar Hayat, Chief Drugs Controller. Punjab apprised the Board about theobservations made by the inspection team during the visit of the firm. In the light of the facts stated in the inspection report, the Board observed that

- The firm has registration of plain tablets of mefenamic acid but it was manufacturing dispersible tablet which is illegal Moreover, the firm is manufacturing mefenamic acid dispersible tablets, the reference of which is neither available in any pharmacopeia nor such reference is available for its manufacturing by any firm in the world
- The defect in the tablet was due to improper development of dispersible tablet formulation and that the firm has not performed any in-vitro tests or study to evaluate the stability of dispersible formulation.
- The firm was performing only Disintegration test and not performing dissolution test while according to official pharmacopoeia, both tests are necessary to be performed.
- The expiry date of the subject drug is 08/2020 but the firm has still not recalled it from the market.
- According to the letter from DRAP to M/S Opal Laboratories LC-41, LITE, Landhi. Karachi, the management of the firm was changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 &10 November 2017. However, in PQCB 194thmeeting dated 18-10-2018, the current CEO of the firm appeared before the Board and stated that the firm has been acquired by the new management in June 2017. The subject drug was manufactured in September 2017 i.e.. after the new management acquired the firm Moreover, no sale deed has been provided by the firm about handing/taking over of the firm, in support of the claim that on such date they were having the responsibility of this offense or not. Further, in writ petition no. 24146/2019 as reflected by the orders of Ayesha A. Malik J dated 16-05-2019, the petitioner has not taken any such stance rather he was in the proper defense of case in the High Court in said writ petition.

Keeping in view the foregoing facts, the Board unanimously decided to uphold its previousdecision for grant of permission for Prosecution against the following accused in the Drug Court

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of:

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

The Board further decided to recommend the Registration Board, Drug RegulatoryAuthority of Pakistan for cancellation of registration of Tablet Dologin (Mafenamic acid) 250mg manufactured by M/S Opal Laboratories LC-41, LITE, Landhi, Karachi.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 25: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOPRIN TABLETS 75MG, B# 006502L, MANUFACTURED BY M/S PACIFIC PHARMACEUTICALS (PVT.) LTD., 30TH km MULTAN ROAD, LAHORE.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-453-07/2016 dated 30-11-2019 has informed that Provincial Inspector of Drugs Tehsil Rajan Pur reported that:

i. He, on 12-05-2016, inspected the Medical Store Depot, E.D.O (Health) Office Rajan pur and took samples of two different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of two drug samples after test/ analysis was declared as **Sub-standard** by Government Analyst Drug Testing Laboratory Multan, as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet Doloprin 75mg	006502L	M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan.	TRA NO.5598/DTL dated: 18-06- 2016	**Test/Analysis with Specifications:** Manufacturer's Specifications **Description:** Round pink tablets, packed in outer carton. Some tablets have spots and irregular surface. **(Does not comply with Specifications).** **Assay: (Aspirin)** Stated: 75mg/Tablet Found: 75.80mg/Tablet Percentage: 101.07% Limit: 90-110% **Result:** The sample is **Sub-Standard** on the basis of physical specifications.

iii. Store keeper of Medical Store Depot, E.D.O (Health) Office, Rajan pur provided invoice/ warranty No.PPL/001 dated 04-04-2016 issued by M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, as a proof of its purchase.

iv. A copy of test report and warrantor portion of drug sample was sent to M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30tn Km, Multan Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response they requested for retest/analysis of drug sample from Appellate Laboratory NIH, Islamabad.

v. Pursuant to their request, the sample was sent to NIH Islamabad, from where the drug sample was declared **Substandard** as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results Name of drug
				Analysis with Specifications: B.P 2013 **Description:** Pink colored circular, biconvex, coated, plain tablets, packed in blister packing further packed in outer carton.

Dissolution:	Determined:	Limit:
Acid Phase	3.135	NMT 5.0%

Tablet Doloprin 75mg	006502 L	M/S Pacific Pharmaceutical. (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan.	No. 0131-P/2016 dated 13-10-2016	Buffer Phase **40.37%** NLT 70.0% of the labeled amount (**Does not comply with BP-2013).** **Assay: (Aspirin)** Stated: 75mg/Tablet Found: 78.34mg/Tablet Percentage: 104.45% Limit: 95-105% **Result:** The sample is of **Sub-Standard** quality as defined in the Drug Act, 1976.

vi. Copy of NIH report was sent to M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard.

vii. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of:

a. **Manufacturing for sale/sale of Substandard Drug**

b. **Issuance of false warranty**

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB 194th meeting held on 18-10-2018

Case was considered by the Provincial Quality Control Board, under section11 of the Drugs Act, 1976 in its **194th meeting held on 18-10-2018.** Secretary PQCB apprised the Board that the personal hearing notice was duly served to the accused persons through M&P Courier Service.

Counsel of firm Haroon Dugal (Barrister) appeared before the Board and submitted that the appearance of spots on the surface of tablets may be due to temperature or storage conditions of the drug sample. He further added that the QC unit of firm has retested the retained samples and they are according to specifications both physically and chemically. Keeping in view the foregoing facts, the Board with due deliberation and discussion at length unanimously decided to **adjourn the case** in the best interest of justice due to its **incomplete quorum** as the presence of Secretary DQCB is mandatory to complete the quorum of the meeting under law.

Personal hearing notice(s) issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **208thmeeting held on 27-06-2019.** Mr. Sadiq Hussain Secretary DQCB District Rajanpur was present along with original record of the case.

Slama Imran (Representative of the firm) appeared before the Board on the behalf of **M/s Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore** and stated that the same batch no. of subject drug sample has been declared of standard quality from DTL Faisalabad and Rawalpindi. He further added that the drug in question is substandard on the basis of dissolution test. According to USP, if a drug sample failed to comply with its dissolution test it should be repeated. Hence in the instant case, analyst of NIH Islamabad failed to repeat the test.

The Board, after detailed scrutiny of the case record and statement of therepresentative of the firm, observed that matter for subject drug need to be evaluated. So, in order to dig out the root cause of this defect the Board decided to constitute a committee comprising of the followings for the Product specific inspection of **M/s Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan** to submit report within fortnight for consideration by the Board:

1) **Prof. Dr. Mahmood Ahmed** Convener
Member PQCB

2) **Mr. Munawar Hayyat** Member
Member PQCB

3) **Mrs. Rabeea Sultan** Facilitator

PRODUCT SPECIFIC INSPECTION REPORT

Members of inspection committee:

Prof. (Rtd.) Dr. Mahmood Ahmad	*Member Board (PQCB)*	*Convener*
Dr. Muhammad Munawar Hayat	*CDC Punjab*	*Member*
Ms. Rabeea Sultan	*Incharge Regulatory Wing PQCB*	*facilitator*

Date of Inspection: 31-07-2019

Inspection was conducted with reference to PQCB order no. ***PQCB/R-453-07/2016*** *dated 02-07-2019. Tablet Doloprin 75mg, batch no. 006502L was declared substandard vide DTL test report no. 5598/DTL dated: 18-06-2016 from DTL Multan based on physical specifications i.e. Round pink tablets, packed in outer carton. Some tablets have spots and irregular surface. The sample was sent to NIH on request of the firm from where the sample was declared substandard based on dissolution test i.e., only 40.37% of the labeled amount of the tablet was found in buffer phase however B.P requires that it should not be less than 70.0% of the labeled amount.*

Premises:

The manufacturing unit was established in 1990.lt is MHRA certified pharmaceutical company having 180 finished products and exporting up to 28 countries. It is ISO 1400:2004 certified Pharmaceutical Company by SGS. The manufacturing unit comprises of two main blocks. In first block there is tablet section, capsule section, syrup section and semi-solid section. While in second block there are dedicated sections for narcotics, anti-tuberculosis drugs and hormones. Manufacturing area and Q.C is located on the ground floor while the administration department is on the first floor of the building. The drug in question i.e., Doloprin 75mg tablets enteric coated tablet was registered vide letter No.F.3-2/98-REG.II(M-133) dated 20-05-1998 having registration No.021647.

Detail of Product:

Doloprin 75mg Tablet, Batch No. 006502L, Date of Mfg. 02-16. Exp. Date 01-19

Technical Staff

Designation	*Name*
Director/ Quality Control In	*Ahmed Junaid Rashid*
Production In charge	*Imtiaz Hussain*
QC Manager/warrantor	*Imran Shehzad*

Detail of Inspection/Observations:

1. *Product Specification of tablet doloprin 750mg is B.P 2013 specification. Since registration B.P method is used for testing. The primary reference standard available was USP aspirin having Lot no R059RO.*
2. *The temperature and humidity charts were displayed and filled accordingly. At the time of inspection temperature in Raw Material Store was 24°C and humidity was 48%.*
3. *There were proper air showers, cross over bench and separate entrance and change rooms for male and female staff.*
4. *Raw Material Store of the unit has designated dusting area, quarantine area, rejection area and sampling area.*
5. *HVAC system is installed and is operational.*
6. *Mixing area has three rooms for mixers, where two mixers having capacity of 200kg and 1 mixer having capacity of 100kg are present. There is a separate room for fluidized bed dryer having capacity of 100kg and two rooms for wet granulation. The final mixing is done in V-mixer which has*

a capacity of 700kg. Most of the batches are of 200kg.

7. *In production area temperature, humidity and differential pressure were properly maintained and manometric devices were in order.*

8. *In compression room-1 compression of tablet plasenzym was in process the temperature and humidity was 26°C and 48% respectively. In compression room-2 compression of tablet Glupac SR in compression room-3 compression of tablet levopraid 25mg was in process the temperature and humidity were well maintained. Compression room no.04 was temporary in process quarantine at the time of inspection.*

9. *In capsule section the temperature and humidity at the time of inspection was 24.9°C and 52% respectively. The capsule filling machine was fully automatic attached with dust collectors etc. having filling capacity of 800cap /min. The section had a portable polisher as well.*

10. *The unit has automatic machines for sugar coating, enteric coating and film coating. During inspection spray coating of tablet Bromelin was in process in coating room no.02.*

11. *General liquid section has 09 storage tanks with different storage capacities. Manometric devices were properly installed and differential pressures were well maintained.*

12. *Personnel and materials entry are separate in manufacturing area.*

13. *There is a proper transfer gallery in manufacturing area.*

14. *There are 03 rooms for blistering and the machines of the blistering area are attached to conveyer belts of the packing area in a proper flow. At the time of inspection packing was in process on the four belts and the temperature and humidity of the packing hall was 27.3°C and 51% respectively.*

15. *The Quality Control Section has wet chemistry lab, in process quality control Lab. microbiological lab and instrumental lab. All the labs are well equipped having 05 HPLC, FTIR. Kai Fischer, viscometer, digital polarimeter, U.V spectrophotometer, atomic absorption spectrophotometer, potentiometer, automatic dissolution apparatus, filtration pump, muffle furnace, disintegration apparatus, friabilator, hardness tester, etc.*

16. There is a separate stability room having total 05 stability chambers where real time, accelerated and intermediate stability studies are done for hot plate real time stability chamber and accelerated stability chamber etc.

17. All 05 HPLC are operational and are fully automated, analysts working on HPLC are assigned specific login id and password and once an analysis is done and result is generated no change can be done.

18. *During inspection HPLC data of doloprin tablet batch no Al 0212N was checked from record. It was analyzed on HPLC on 30-01-2019.The standard and sample curves of chromatograms were checked and was found to be 6.1 and 6.092 respectively and it was verified with the QC results from the record which was found to be within the specified limits.*

19. *Log book of columns C18 (300x3.9mm) and (250X4.6mm) of the HPLC was checked during inspection it was well maintained.*

20 Operational safety alarms, air showers, smoke detector and insect killers are installed in all sections.

21. SOP for finished product testing having document no. QCFG/03/0017 Revision no.01 dated 26-07-2016 was checked and the method for testing was in accordance with the test and method specified in B.P.

Batch Processing Record of specific product:

1. *BMR Record: available.*
2. *QC retain sample. Not Available. Expired on 01-2019*
3. *Batch size. 800,000 tablets*
4. *Testing method: B P 2013*
5. *Bulk weight: 132000kg*
6. *Theoretical yield= 800,000tabs*
7. *Practical yield=805,860tabs*
8. *Manufacturing started on 16-02-2016*
9. *Labelling / Packing: 01-03-2016*

10. *Expiry date: 01/2019.*
11. *Percentage purity of API=100.27%*
12. *API issued was 60 kg per batch.*
13 *In process QC: Available*
14 *Reconciliation sheet: available*
15. *Record of in-process testing of Doloprin 75mg tablets and chromatograms of batch no.006502L were thoroughly checked. According to BMR of the subject batch dissolution test was conducted on 16-02-2016 and following results were obtained.*

Tablet	*%age release in 0.1 N HCI in first 02 hours*	*%age release in 6.8 Phosphate buffer after 01 hour*
1	*3.54%*	*85.82%*
2	*3.54%*	*93.85%*
3	*3.96%*	*91.69%*
4	*3.34%*	*92.31%*
5	*2 50%*	*83.66%*
6	*3.34%*	*90.76%*
Average	*3.37%(NMT 5%)*	*89.68%(NLT 70%)*

16. *Record of finished product testing of Doloprin 75mg tablets and chromatograms of batch no.006502L were also thoroughly checked. According to BMR of the subject batch dissolution test was conducted on 04-03-2016 and following results were obtained.*

Tablet	*%age release in 0.1 N HCI in first 02 hours*	*%age release in 6.8 Phosphate buffer after 01 hour*
1	*2.96%*	*99.49%*
2	*2.75%*	*99 80%*
3	*2.75%*	*100.12%*
4	*2.96%*	*99.80%*
5	*2.53%*	*97.59%*
6	*2.53%*	*99.80%*
Average	*2.75% (NMT 5%)*	*99.43%(NLT 70%)*

18. *Testing of finish product is as per specification and assay of finished product prior to release in FGS was 99.79%.*
19. *Aspirin was purchased from Ali Baba Chemicals and according to COA its assay was 100.27%.*

Conclusion:

The panel is of the opinion that

1. *The drug was declared substandard by Govt. Analyst. Drug Testing Laboratory, Punjab was on physical ground having spots and rough surface of the tablet whereas declared substandard by NIH on dissolution test. From reflecting the different aspects, the inspection was conducted in derail to address all parameters of manufacture to correlate the any defect in manufacturing, but not found.*
2. *Remedial measures were taken by the firm by improving the standards of manufacturing at all levels.*
3. *No record for recalling the drug product was provided by the firm.*
4. *No CAPA was generated by the firm and Root-cause analysis was not performed.*

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11of the Drugs Act 1976 in its **214th meeting held on 30-11-2019.** Secretary DQCB Rajanpur Mr Sadiq Hussain and Drug Inspector Rajanpur Mr. Rauf Ahmed Meo both were present with original case file. Prof. (R) Dr.

Mahmood Ahmad (Convener of PSI Committee) apprised the Board about findings and conclusion of the PSI Committee. Panel was of the opinion that no CAPA was generated by the firm and Root-cause analysis was not performed. Moreover, no record for recalling the drug product was provided by the firm.

Counsel of the firm Advocate Shahzaib Bhatti and accused Imtiaz Hussain(Production Incharge) appeared before the Board and submitted the following grounds/remedial measures taken by firm.

i. Warrantor and retained sample portion were thoroughly checked and found to be of standard quality in all parameters.

ii. Our Quality Assurance Department is well established and working properly.

iii Each batch is released by QC Department after though examination by international standard test/ analysis via sophisticated HPLC Methods. HPLC Trails are present showing all the results of standard quality.

iv We have proper SOP for batch recall and until now three volunteer recalls have done in the past at different levels.

v. The batch in question was of 8 lakh tablets and supplied to institution as well in market. Upon receipt of substandard report a distributer level recall was done regarding the batch. He requested the Board for lenient view.

The Board, after detailed scrutiny of NIH report and PSI report observed that noCAPA was generated by the firm and Root-cause analysis was not performed. No record for recalling the drug product was provided by the firm. According to NIH report the drug was having a very poor release profile as only 40.37% (instead of >70%) drug was released in buffer Phase. Prof. Dr. Irshad Hussain Qureshi (Professor of Medicine/ Member PQCB) was of the opinion that such low quantity of released drug is unable to produce its therapeutic effect. He was of the opinion that DRAP should review the registration of the product in light of this NIH report and guidelines for manufacturer should be issued to improve release profiles for such formulations. Moreover, unnecessary use of platelet inhibitors (e.g. Aspirin) should be discouraged as this may increase the risk of brain hemorrhage by causing small capillary rupture by blood thinning effect.

In view of foregoing facts, the Board after due deliberation and discussion decided to grant **permission for prosecution** against the following accused persons in theDrug Court:

i. M/s Pacific Pharmaceuticals, (Pvt.) Ltd., 30th KM, Multan, Lahore through its Director Junaid Rashid.
ii. Ahmad Junaid Rashid — Director/Quality Control Incharge.
iii. Imtiaz Hussain — Production Incharge.
iv. Faisal Imran — Marketing Incharge.
v. Imran Shahzad — Warrantor/QC Manager.

Of M/s Pacific Pharmaceuticals, (Pvt.) Ltd., 30th KM, Multan, Lahore for the offences of

a) **Manufacturing for Sale/ Sale of Substandard Drug**
b) **Issuance of its false warranty**

The Board further endorsed the comments of Prof. Dr. Irshad Hussain Qureshi and decided to recommend DRAP to review the registration of the subject drug in light of the NIH report and guidelines for manufacturers should be issued to improve release profiles for such enteric coated formulations. Moreover, Dispersible formulation of Aspirin instead of enteric coated formulation should be promoted as drug release defects in enteric coated formulations are more common.

The Board further recommended the Director Registration Board, DRAP, Islamabad to review the Registration of the Subject Drug.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Proceeding & decision of 296th meeting of Registration Board.

Member of Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) read the article 13 of the constitution of Pakistan and is reproduced as under;

> **"13.** *No person-*
>
> *(a) Shall be prosecuted or punished for the same offence more than once; or*
>
> *(b) shall, when accused of an offence, be compelled to be a witness against himself."*

Furthermore, he also discussed the Punjab drug rules, 2007 wherein he read the sub rule (3) of rule 5 and is reproduced as under;

> *"(3) The Provincial or the District Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the Rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

The member of Law & Justice Division () further added that in view of the above said facts it is evident that Provincial Quality Control Board can only take one action under the Punjab Drug Rules 2007, i.e.

i. Either grant the permission for prosecution against the accused in the court of competent jurisdiction

OR

ii. Recommending suspension or cancellation of his license to the licensing authority

Decision of the 296th meeting of Registration Board:

The Board after thorough deliberation, considering the facts of the case and comments of the Member Law & Justice Division decided that since the prosecution has already been granted against the accused person(s) by PQCB Punjab therefore, any other action against the accused would attract double jeopardy. Hence, the Board decided to refer the case back to the PQCB Punjab as the recommendations cannot be considered keeping in view the legal position recorded above.

Case No. 26: Manufacture & Sale of Sub-Standard Drug Revox 500mg Tablets Batch No. 17GT01 Reg. No. 045265 manufactured by M/S Uni-Teich Pharmaceutical (Pvt.) Ltd. Karachi.

FID-II Karachi visited the premises of M/s Uni-Tiech Pharmaceutical (Pvt.) Ltd., Plot No.4/116, Sector-21 Korangi Industrial Area, Karachi on 23-10-2017 and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3:

Name:	Revox 500mg Tablets
Composition:	Each tablet contain 500mg Levofloxacin.
Registration No:	045265
Batch No:	17GT01
Manufacturing Date:	07-17
Expiry Date:	07-19
Manufactured By:	M/s Uni-Teich Pharmaceutical (pvt) Ltd, Plot No. 4/116, Sector-21 Korangi Industrial Area Karachi.

02. The FID-II, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.MK-223 to 225/2017-FID-II (K) dated 23-10-2017 as required under Section 19(3)(i) of the Drugs Act, 1976.

03. The FID-II, Karachi has also forwarded one sealed portion of sample as Board's Portion vide letter No.MK-223 to 225/2017-FID-II (K) dated 23-10-2017 as required under Section 19(3)(ii) of the Drugs Act, 1976.

04. The Federal Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of dissolution** vide test/analysis **report No. KQ.586/2017** dated 13th December, 2017.

05. The area FID-II, Karachi vide letter No. MK-223 to 225/2017-FID-II (K) dated 18-12-2017 has asked the M/s Uni-Tiech Pharmaceutical (Pvt.) Ltd., Plot No.4/116, Sector-21 Korangi Industrial Area, Karachi to explain their position in the matter of manufacturing and selling of Adulterated and substandard drug.

06. M/s Uni-Tiech Pharmaceutical (Pvt.) Ltd., Plot No.4/116, Sector-21 Korangi Industrial Area, Karachi submitted their reply vide letter No. Nil dated 11th January, 2018 wherein they have requested to retest the Board's portion from Appellate Laboratory, NIH, Islamabad.

07. On the request of the firm, sample was sent for retesting from Appellate laboratory, NIH, Islamabad dated 09th February, 2018 under section 22(5) of the Drugs Act, 1976 after seeking due approval from the Chairman, Registration Board (in exercise of delegated power of Registration Board in it 283rd Meeting held on 27 to 29th June, 2018) as required U/S 22(5) of the Drugs Act, 1976.

08. The Appellate Laboratory – NIH, Islamabad vide their test report No. 04-M/2018 dated 13th March, 2018 declared the sample as of **Substandard quality on the basis of dissolution (Found:57.92%, Limits: Not less than 80% after 30 minutes)**.

09. The FID-II, Karachi provided M/s Uni-Tiech Pharmaceutical (Pvt.) Ltd., Plot No.4/116, Sector-21 Korangi Industrial Area, Karachi is involved in manufacturing and selling of Substandard drug and violated the section 23(1)(a)(v) of the Drugs Act, 1976 and rules framed there under and provided the names of responsible persons/ technical persons which are as under:

S.No.	Name	Designation
1	Dr. Abdul Shakoor Usman	Managing Director
2	Syed Fida Hussain	Q/C Manager
3	Muhammad Hashim	Production Manager

10. The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-II, Karachi and provided the following names being responsible persons and technical persons.

M/s Uni-Teich Pharmaceutical (pvt) Ltd,
Plot No. 4/116, Sector-21 Korangi
Industrial Area Karachi,

Ms. Saira Shakoor **(Director)**
M/s Uni-Teich Pharmaceutical (pvt) Ltd,
Plot No. 4/116, Sector-21 Korangi
Industrial Area Karachi

Syed Fida Hussain, **(Quality Control Incharge),**
M/s Uni-Teich Pharmaceutical (pvt.) Ltd,
Plot No. 4/116, Sector-21 Korangi
Industrial Area Karachi,

Mr. Abdul Shakoor **(Director)**
M/s Uni-Teich Pharmaceutical (pvt) Ltd,
Plot No. 4/116, Sector-21 Korangi
Industrial Area Karachi

Muhammad Hashim, **(Production Incharge)**
M/s Uni-Teich Pharmaceutical (pvt) Ltd,
Plot No. 4/116, Sector-21 Korangi
Industrial Area Karachi,

11. Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 3-65/2017-(QC) dated 19-11-2018 that why the following action(s) should not be initiated against you:

i. Prosecution in the Drug Court.
ii. Cancellation/Suspension of Drug Registration.
iii. Any other action the Board may deem fit.

12. The show cause notice was served to the firm and accused persons but the firm did not submit their reply in response to show cause notice.

Proceeding and Decision of the 287th Meeting of Registration Board.

Mr. Muhammad Hashim (Production Manager) of M/s Uni-Teich Pharmaceutical (pvt.) Ltd, Plot No. 4/116, Sector-21 Korangi Industrial Area, Karachi appeared on behalf of M/s Uni- Teich Pharmaceutical (pvt.) Ltd, Plot No. 4/116, Sector-21 Korangi Industrial Area, Karachi to plead instant case of Substandard drug Sub-Standard Revox 500mg Tablets Batch No.17GT01 Reg. No. 045265 before the Board in its 287th meeting on 04th January, 2019.The Board after hearing the accused deliberated the matter in depth in the light of available record/investigation report of FID decided as under:

i. Submission of product development data by the firm.
ii. Product Specific Inspection including verification of product development data by the following panel:
    - Director, Drug Testing Laboratory, Karachi.
    - Area Federal Inspector of Drugs.
iii. Suspension of the Registration of the said product for six (06) months or till the verification of data and satisfactory report by the panel whichever is later.

The above said decision of the Registration Board was communicated to the quarter concerned vide No.F.03-92/2018-QC (287-RB) dated 28th February, 2018.

FID-II, DRAP, Karachi vide reference No.F.03-02/2020-FID-II (K) forwarded the Product Specific Inspection report of the subject cited drug. The report forwarded by the FID, DRAP, Karachi is reproduced as under;

Ms. Uni-Tiech Pharmaceuticals (Pvt.) Ltd, situated at Plot No.4/116, Sector-21 Korangi Industrial Area Karachi was visited & inspected on 30/01/2020 as per instructions contained in DRAP Islamabad Letter No. F.03-92/2018-QC (287-RB), Dated: 28th February 2019. Mr. Munsif Ali Qureshi Plant Manager, Muhammad Hashim Production Manager, Miss. Ameer Zaadi QC Manager and other technical persons from respective departments assisted during the course of inspection. Followings are the detailed observations and recommendations of the visit.

HISTORY OF THE CASE:

1. *Samples of Tablet Revox-500mg Batch No. 17GT01were taken 23/10/17 during routine inspection of the then FID.*
2. *The said samples were sent to FGA CDL Karachi for testing on 24/10/17.*

3. *The FGA CDL Karachi declared the above sample as of Sub-standard quality based on Dissolution test; vide the test report No.KQ-586/2017 Dated: 13/12/17.*

4. *After FGA CDL report, the firm requested for retesting of their sample from NIH Islamabad as per law.*

5. *The Chief Analyst NIH Islamabad Vide test report No.04-M/2018, Dated: 13th March 2018, maintained the results of FGA CDL Karachi and declared the samples as of Sub-standard quality based on same Dissolution Test.*

6. *The Drug Registration Board in its 287th Meeting on 03rd& 04th January 2019, after listening Firm's point of view decided to suspend the registration of said product for six month or till the verification of product development data and satisfactory report by the panel.*

CURRENT OBSERVATIONS OF THE PANEL:

1. *The panel observed that the firm has kept the production of Tablet Revox-500mg suspended after the decision of Board concerned. Relevant manufacturing records in this respect including procurement of raw material, packaging materials, sales record and log-books were carefully checked and observed that the firm has not manufactured any commercial batch of Tablet Revox-500 mg since its suspension.*

2. *During the suspension period the firm started to redevelop the product and three trial batches (Each consists of 5000 Tablets) of the said product had been manufactured with revised formulation. Sufficient quantities of trial batches were kept on accelerated stability studies in a qualified climatic chamber. Manufacturing processes in this respect were validated as per protocols in place. Active material was obtained from ZAFA Pharmaceuticals Karachi. The trial batches were manufactured under appropriate GMP conditions as observed from BMR.*

CONCLUSION:

The panel after reviewing relevant data & physical inspection of the QC Lab and production section observed that three trial batches of Tablet Revox-500 MG were manufactured and each batch yielded the satisfactorily results during manufacturing & under stress stability conditions, especially Q value of Dissolution Test fallen within the specified limits.

RECOMMENDATIONS:

Based on the stated observations and keeping in view the attitude of the management towards continuous improvements, the panel unanimously recommends to the Board concerned, the resumption of production of Tablet Revox-500 MG as the necessary suspension period has been passed and the firm has satisfactorily carried out the product development studies of under reference product as well.

Proceedings & Decision of 296th Meeting of registration Board.

Registration Board decided to refer back report to the panel for determining / confirmation of Root Cause Analysis and CAPA emerged after the report.

Additional Agenda Minutes

Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Case No. 01 PRIORITY REGISTRATION APPLICATIONS OF POTASSIUM IODIDE TABLETS

Drug Regulatory Authority of Pakistan in its 88th meeting held on 7th August, 2020 discussed the application of Pakistan Atomic energy Commission (PAEC) for the registration of Potassium Iodide tablets. In order to facilitate & expedite the process of registration of Potassium in order to facilitate & expedite the process of registration of Potassium Iodide tablets; the Authority exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713 (1)/2018 dated 8th June, 2018 allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5-F, for registration of Potassium Iodide tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions;

i. The applicants can submit their applications till 30-09-2020 and these applications will be considered out of queue.

ii. Registration Board shall consider grant of registration and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required

Proceedings & Decision:

The Registration Board considering the above cited Authority's decision regarding priority consideration of Potassium Iodide tablets in light of approvals granted by the reference regulatory authorities decided upon the following applications as mentioned against each case:

1.	**Name and address of manufacturer / Applicant**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	**Biodat 130mg Tablet**
	Composition	Each tablet contains: Potassium Iodide…130mg
	Diary No. Date of R& I & fee	Dy. No 22668 dated 04-09-2020, Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	13-2-2020, GMP was compliant on the day of inspection.
	Remarks of the Evaluator.(VI)	Reference product is uncoated.
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
2.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	**KI 130mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…130mg

	Diary No. Date of R& I & fee	Dy.No 22666 dated 04-09-2020 Rs.20,000/- dated 03-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	CGMP certificate valid till 10-7-2022.
	Remarks of the Evaluator.(VI)	
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
3.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	**KI 65mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…65mg
	Diary No. Date of R& I & fee	Dy.No 22665 dated 04-09-2020 Rs.20,000/- dated 03-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	4's, 1x10's, 10'sx10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Orin 65mg Tablet of M/s Tabros Pharma (Reg.# 032360)
	GMP status	CGMP certificate valid till 10-7-2022.
	Remarks of the Evaluator.(VI)	Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
4.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi
	Brand Name +Dosage Form + Strength	**Thiodide 65mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…65mg
	Diary No. Date of R& I & fee	Dy.No 22785 dated 04-09-2020 Rs.50,000/- dated 04-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5D
	Finished product Specification	USP
	Pack size & Demanded Price	4's, 1x10's, 10'sx10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Orin 65mg Tablet of M/s Tabros Pharma (Reg.# 032360)
	GMP status	CGMP certificate issued and is valid till 24-9-2021
	Remarks of the Evaluator.(VI)	Stability data are not submitted. Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies	

	for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
5.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi
	Brand Name +Dosage Form + Strength	**Thiodide 130mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…130mg
	Diary No. Date of R& I & fee	Dy.No 22786 dated 04-09-2020 Rs.50,000/- dated 04-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5D
	Finished product Specification	USP
	Pack size & Demanded Price	4's, 1x10's, 10'sx10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	CGMP certificate issued and is valid till 24-9-2021
	Remarks of the Evaluator.(VI)	Stability data are not submitted.
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
6.	Name and address of manufacturer / Applicant	M/s Ameer Pharma Pvt Ltd. 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	**Thyromeer 65 Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…65mg
	Diary No. Date of R& I & fee	Dy.No 22804 dated 07-09-2020 Rs.50,000/- dated 04-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Orin 65mg Tablet of M/s Tabros Pharma (Reg.# 032360)
	GMP status	9-12-2020, and 26-1-2020 The panel recommend the renewal of DML.
	Remarks of the Evaluator.(VI)	Form-5 is applied. Stability data are not submitted. Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
7.	Name and address of manufacturer / Applicant	M/s Ameer Pharma Pvt Ltd. 23 KM-Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	**Thyromeer 130mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide…130mg
	Diary No. Date of R& I & fee	Dy.No 22805 dated 07-09-2020 Rs.50,000/- dated 04-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5

	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	9-12-2020, and 26-1-2020 The panel recommend the renewal of DML.
	Remarks of the Evaluator.(VI)	Form-5 is applied.
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
8.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	**Idosol 130mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide Eq. to 100mg of Iodine…130mg
	Diary No. Date of R& I & fee	Dy.No 22900 dated 07-09-2020 Rs.20,000/- dated 07-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	Last GMP inspection conducted on 29-05-2017, 30-05-2017 & 13-07-2017, 03-04-2017 and report concludes that panel recommends the grant of drug manufacturing license.
	Remarks of the Evaluator.(VI)	
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
9.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	**Idosol 65mg Tablet**
	Composition	Each Tablet Contains: Potassium Iodide Eq. to 65mg of Iodine…50mg
	Diary No. Date of R& I & fee	Dy.No 22901 dated 07-09-2020 Rs.20,000/- dated 07-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Orin 65mg Tablet of M/s Tabros Pharma (Reg.# 032360)
	GMP status	Last GMP inspection conducted on 29-05-2017, 30-05-2017

		& 13-07-2017, 03-04-2017 and report concludes that panel recommends the grant of drug manufacturing license.
	Remarks of the Evaluator.(VI)	Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
10.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	IOD-K 65mg Tablet
	Composition	Each Tablet Contains: Potassium Iodide…65mg
	Diary No. Date of R& I & fee	Dy.No 23180 dated 08-09-2020 Rs.50,000/- dated 08-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5D
	Finished product Specification	USP
	Pack size & Demanded Price	10's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Orin 65mg Tablet of M/s Tabros Pharma (Reg.# 032360)
	GMP status	3-5-2019 Firm was operating under good level of GMP compliance.
	Remarks of the Evaluator.(VI)	Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
11.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	IOD-K 130mg Tablet
	Composition	Each Tablet Contains: Potassium Iodide…130mg
	Diary No. Date of R& I & fee	Dy.No 23181 dated 08-09-2020 Rs.50,000/- dated 08-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5D
	Finished product Specification	USP
	Pack size & Demanded Price	10's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Reg # 036721 Bosch Pharma
	GMP status	3-5-2019 Firm was operating under good level of GMP compliance.
	Remarks of the Evaluator.(VI)	
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	
12.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi

	Brand Name +Dosage Form + Strength	SLO-K 65mg Tablet
	Composition	Each Tablet Contains: Potassium Iodide Eq. to 50mg of Iodine
	Diary No. Date of R& I & fee	Dy.No 23179 dated 08-09-2020 Rs.50,000/- dated 08-09-2020
	Pharmacological Group	Antidote
	Type of Form	From-5D
	Finished product Specification	USP
	Pack size & Demanded Price	10's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	
	GMP status	11-06-2018, firm is operating at good level of GMP Compliance.
	Remarks of the Evaluator.(VI)	Me-too status is not confirmed
	Decision: Approved. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.	

Case No. 02 PRIORITY REGISTRATION OF FLUDROCORTISONE TABLETS

The Drug Regulatory Authority of Pakistan in its 91st meeting held on 4th September 2020, exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F, for Registration of Fludrocortisone tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

a. *The applicants can submit their applications till **30-09-2020** and these applications will be considered out of queue.*

b. *Registration Board may consider grant of registration and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required.*

Proceedings & Decision:

The Registration Board considering the above cited Authority's decision regarding priority consideration of Fludrocortisone tablets, in light of approvals granted by the reference regulatory authorities decided upon the following applications as mentioned against each case:

13.	**Name and address of manufacturer / Applicant**	**"M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi"**
	Brand Name +Dosage Form + Strength	Fludrocort 0.1mg Tablet
	Composition	"Each Tablet Contains: Fludrocortisone Acetate…0.1mg"
	Diary No. Date of R& I & fee	Dy. No 44230 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Mineralocorticoid
	Type of Form	Form-5D
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 6.25/- per tablet Rs. 125/- per 20's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	--
	GMP status	Last inspection report 07-02-2018 concluding as under: On the basis of current inspection, it was observed that the firm rectified all observations noted during last GMP Inspection
	Remarks of the Evaluator[2]	• Evidence of required manufacturing facility required. • Evidence of me-too status required.
	Decision of 289th meeting: Deferred for following: • Evidence of approval of required manufacturing facility for applied formulation from CLB.	

	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC: Firm has been granted section approval vide letter issued by Secretary CLB dated 27-09-2019, declaring approval of following two sections for M/s Tabros Pharma. • Tablet General - Amendments (granulation area) • Tablet (Steroid) Regularization
	Decision: Approved for manufacturing in Tablet (Steroid) section. Registration letter will be processed after submission of differential fee of Rs. 30,000/-. The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration.

Case No. 3: GUIDANCE DOCUMENT FOR SUBMISSION OF APPLICATION ON FORM 5-F (CTD) FOR REGISTRATION OF PHARMACEUTICAL DRUG PRODUCTS FOR HUMAN USE.

Registration Board was apprised that in its 293rd meeting, explanatory notes for Form 5-F (CTD) were approved. Later, PE&R Division transformed these explanatory notes into a guidance document with detailed explanation for each module and section of Form 5F (CTD). This guidance document will facilitate the applicants on the related requirements in step by step manner.

Registration Board was apprised about instant guidance document covering 5 modules with details. The Board approved the subject guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use and also appreciated the continuous efforts of PE&R Division for preparing a comprehensive document for effective implementation of Form 5F (CTD). The detailed document is explained as under:

GUIDANCE DOCUMENT FOR SUBMISSION OF APPLICATION ON FORM 5-F (CTD) FOR REGISTRATION OF PHARMACEUTICAL DRUG PRODUCTS FOR HUMAN USE

Document No.: **GL No. DRAP/PER-000/04**
Document History: **1st Edition**
Effective Date:

Drug Regulatory Authority of Pakistan
Islamabad - Pakistan.

Table of Contents

1. HISTORY

This is the first edition of these guidelines.

APPLICATION[1] - Guidance for Industry

This document is applicable to the firms who intends to apply for registration / Marketing Authorization of pharmaceutical drug products for human use.

2. SCOPE

The scope of this Guideline is limited to application on Form-5F (CTD) for registration of pharmaceutical drug products for human use.

3. BACKGROUND

Section 7 (c) (ix) of DRAP Act 2012, mandated the systematic implementation of internationally recognized standards of World Health Organization, International Conference on Harmonization (ICH), and Food and Drug Administration guidelines etc.

These guidelines conform and shall be read in consistence to DRAP Act, 2012 and Drugs Act 1976 and Rules framed there under.

[1] The Guidance document is prepared by Drug Regulatory Authority of Pakistan for better illustration of data requirements of the Form 5-F (CTD). However, content of guidance document only reflects the current thinking perspective of the Authority on the subject and does not create or confer any rights for or on any person and does not operate to bind the Authority or the public.

GLOSSARY

ACRONYMS

API	Active Pharmaceutical Ingredient
BAN	British Approved Name
BCS	Biopharmaceutics Classification System
BP	British Pharmacopoeia
BSE	Bovine Spongiform Encephalopathy
CAS	Chemical Abstract Service
CEP	Certificate of Suitability
CoA	Certificate of Analysis
CPP	Critical Process Parameters
CQA	Critical Quality Attribute
CTD	Common Technical Document
DML	Drug Manufacturing License
DRAP	Drug Regulatory Authority of Pakistan
EPAR	European Public Assessment Report
FDA	Food & Drug Administration of United States
GCP	Good Clinical Practices
GLP	Good laboratory Practices
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonization
INN	International nonproprietary name
IR	Infrared
JP	Japanese Pharmacopoeia
LR&A	Licensing, Registering & Advertising
MS	Mass Spectrometry
NMR	Nuclear Magnetic Resonance
OSD	Oral Solid Dosage form
PAR	Public Assessment Report
Ph.Eur	European Pharmacopoeia
Ph.Int	International Pharmacopoeia
PMDA	Pharmaceuticals and Medical Devices Agency of Japan
RRA	Reference Regulatory Authority
SAE	Serious Adverse Events
TSE	Transmissible Spongiform Encephalopathies
USAN	United States Adopted Name
USP	United States Pharmacopoeia
UV	Ultraviolet-Visible
WHO	World Health Organization

1. INTRODUCTION

This guidance is developed to assist manufacturers and importers in developing their applications for registration of human pharmaceutical drug products. Drug Regulatory Authority of Pakistan (DRAP) has adapted CTD format for registration of all such drugs vide SRO-713(l)/2018 dated 8th June 2018. The detailed guidance regarding the data requirement for CTD format has been provided in ICH M-4 guidelines. Since the DRAP is introducing the CTD in a progressive manner, therefore, initial guidance to applicants would be helpful for harmonization and appropriate data submission to achieve consistency and uniformity of application.

This guidance document is developed on the basis of best available knowledge and scientific data / evidence.

2. LEGAL PROVISIONS

Rule 26 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, as amended vide S.R.O 713(I)/2018 dated 8th June, 2018, under 26(1) section provides the standard formats and requirements for submission of registration application dossier on Form 5F (Common Technical Documents) for registration of Human drugs.

3. GENERAL GUIDANCE FOR APPLICANTS

For submitting applications on CTD format, applicant needs to follow the following general instructions/guidance to ensure proper submission.

1. Module 1 (Administrative part) shall be prepared as provided in Form-5F without deleting any component. Applicant shall mention "Not applicable" with proper justification for those parts which are not related to any particular application.

2. Quality Overall Summary (QOS) in module 2 shall be prepared using WHO QOS-PD template or template provided hereinafter without deleting any component / table of the template. Applicant shall mention "Not applicable" with proper justification for those parts which are not related to any particular application.

3. The Quality overall Summary (QOS) prepared as per WHO QOS-PD template or template provided hereinafter needs to be submitted as "MS Word document" in CD / USB as well.

4. Application shall be submitted along with complete data as per the module 3.

5. Each section / sub section of CTD application shall be properly segregated using page separators.

MODULE 1: (ADMINISTRATIVE PART)

1.1 Covering Letter and Fee Deposit Slip

a) Covering letter on the Applicant company / manufacturer / importer letter head in context to the application for the registration of the Pharmaceutical Drug Product shall be submitted, which shall be dully signed by owner/ authorized person on behalf of company/ manufacturer/ importer as per below mentioned format:

"I / We ……..... of ……hereby apply for registration of the drug, namely ……details of which are enclosed."

b) An original cash deposit slip endorsed by Budget & Accounts Division, DRAP of prescribed fee as per Schedule-F of L R & A Rules, 1976, for specified category shall be attached therewith.

1.2 Table of Contents (From Module 1 to Module 5)

a) A comprehensive Table of Contents shall contain Module and sub module heading with page number on the pharmaceutical dossier. The contents of all the Module from 1 to 5 shall be covered. Comprehensive Table of Contents is different form individual table of contents in the beginning of each Module.

b) Also, a complete list of all documents provided in the registration dossier by Module, Section and sub-section shall be included.

1.3 Applicant Information

1.3.1. Name, address and contact details of Applicant / Marketing Authorization Holder:

a) In this section, administrative information related to the applicant is required.

b) It is necessary to provide the complete particulars of the applicant, which shall contain:

i. Name of Licensed Pharmaceutical Manufacturer / Licensed Importer having Drug Sale License by respective licensing authority

ii. Manufacturing Site Address of Pharmaceutical unit or address of the godown / warehouse in case the applicant is Drug Sale license Holder

iii. Contact details, including postal address, telephone contact number, Fax number, website and email address.

1.3.2. Name, address and contact details of manufacturing site

There could be following three situations:

a) **The applicant is manufacturer**
Provide the details including name, DML number and complete address of the manufacturing site of the applicant (manufacturer).

b) **Contract Manufacturing (The applicant is not manufacturer for the applied product)**
Provide the details including name, DML number and complete address of the manufacturing site of the manufacturer.

c) **Import (The applicant is importer for the applied product)**
Provide the details including name and complete address of the manufacturing site and name of marketing authorization Holder/ Product License Holder for the applied product.
In case multiple manufacturing sites are involved, provide details for each.

1.3.3. Specify whether the Applicant is:

□ Manufacturer
□ Importer
□ Is involved in none of the above (contract giver)
This point requires the status of applicant for the instant product.

The applicant must select one of the above mentioned options. A manufacturer will provide all the requisite information as per Registration procedure of Pakistan, subsequently mentioned in 1.3.4-1.3.5.

- An importer shall provide Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country.
- "c" is for Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976.

1.3.4. Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable.

a) For drug to be locally manufactured, copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
b) For drugs to be imported, copy of valid Drug Sale License (DSL) issued by relevant licensing authority. The address of applicant mentioned on Drug Sale License (DSL) shall match with the information provided in sub-section 4.3.1 and sole agency agreement / letter of authorization between applicant and marketing authorization holder (abroad).

1.3.5. Evidence of approval of manufacturing facility / Approved Section from Licensing Authority

a) To be provided if option **a** or **c** is selected in sub-section 1.3.3
b) Approval letter of the section (Dosage form) in which manufacturing of the applied product is to be carried out needs to be submitted or panel inspection report conducted for renewal of DML or grant of GMP certificate. In case of contract manufacturing, the same documents from the contract manufacturer shall be submitted.
c) GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.

1.3.6. List of already approved registered drugs in this section

The submission against this point is optional

1.3.7. Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance

The submission against this point is optional**.**

1.3.8. Manufacturer's Site Master File and Credential (for importer)

The submission against this point is optional.

1.4 Type of Application

1.4.1. Application is for the registration of:

□ New Drug Product (NDP)
□ Generic Drug Product (GDP)

a) New Drug Product (*Product not already registered in Pakistan*) includes New Molecule/ New strength / New Formulation.
b) It is important to specify here whether the applicant has submitted the CTD for a New Drug Product Registration or a Generic Drug Product.

1.4.1 Pharmaceutical product is intended for:

□ Domestic sale
□ Export sale
□ Domestic and Export sales

a) Applicant needs to clarify whether the applied product (drug product) is intended for sale in domestic market or both for domestic and export market.

b) For Export only registrations application on Form 5F (CTD) is already exempted by the Authority vide its Circular No. F.1-21/2019-Add:Dir. (PE&R) dated06-02-2019.

1.4.2. For imported products, please specify one of following:

- **Finished Pharmaceutical Product Import**
- **Bulk Import and local repacking (specify status of bulk)**
- **Bulk Import Local Repacking for Export purpose only**

This point only pertains to registration applications of drug products for import.
The applicant / importer needs to specify whether the import is of finished pharmaceutical product or of bulk product. In case of bulk import local repack, the applicant also needs to provide following documents:

a) Evidence and GMP status of packing facility for the bulk imported drug to be repacked and batch release.
b) Agreement between the importer and the firm responsible for local repacking in Pakistan.

1.4.3. Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976.

- **□ Domestic Manufacturing**
- **□ Export Purpose Only**

a) Provide notarized copy of Contract manufacturing agreement.
b) Provide documents confirming number of approved sections of the applicant (DML holder).
c) Provide details of already registered drug products of contract giver on contract manufacturing.

1.5 Detailed Information of Drug, Dosage From & Labeling Claims

1.5.1. Generic name with chemical name & synonyms of the applied drug.

The following necessary information shall be provided in this sub-section:

a) (Recommended) International Non-proprietary name (INN):
b) Compendia name, if relevant:
c) Chemical name(s):
d) Chemical Abstracts Service (CAS) registry number: (where applicable)

The submission of following is **optional**

a) Company or laboratory code:
b) Other non-proprietary name(s) (e.g. national name, USAN, BAN):

1.5.2. Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit

a) Strength of Active ingredient shall be stated clearly. In case API is in the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.
b) For example, each tablet contains, each ml contains in case of Injectable. However, description like each ampoule / vial contains shall be avoided, or in case of syrup / suspension / dry powder for suspension each 5 ml (after reconstitution) contains etc.

1.5.3 The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance.

a) The proposed brand name shall be justified keeping in view the LASA (Look alike and Sound alike) with specific emphasis on prefix, mid-name and suffix.
b) An undertaking in this regard that the applicant shall be responsible to change the name in case the name resembles with already approved / registered names.

1.5.4 Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned.

a) The applicant needs to submit the proposed pack size as well as demanded price for each pack size.

1.5.5 Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API)

a) Indicate Pharmacological class of the API (drug substance) with proper reference.
b) Also, state the WHO ATC code for each distinct therapeutic indication.

1.5.6 Pharmacopoeial reference / Status of applied formulation

Mention the reference specifications of the finished product (drug product) from the following list

- USP
- BP
- Int. Ph.
- JP

Pharmacopoeia of any Reference Regulatory Authority

- Manufacturer's specifications.
- Specifications as per Innovator's product
- Any other (specify exact reference)
- Any other pharmacopoeia as mentioned in Drug specification rules. (Specify the exact reference).

1.5.7 Route of administration

The applicant needs to specify the exact route of administration for the applied drug product. In case of multiple route of administration, specify all routes of administration.

1.5.8 For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price.

If the applicant has selected Generic Drug Product (GDP) in sub-section 1.4.1, the reference of already registered product including the following details needs to be submitted.

- Brand name
- Manufacturer/Registration holder
- Registration number

If the applicant has selected New Drug Product (NDP) in sub-section 1.4.1 "Not applicable since this is a new drug" needs to be mentioned against this point.

1.5.9 The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention.

Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently.

Mention the name of innovator product in case of non-pharmacopoeial product.

1.5.10 Dosage form of applied drug

- Dosage form of applied drug shall be mentioned clearly, with complete description of a unit like "Film Coated Tablet" & "Sugar Coated Tablet" etc.

1.5.11 Proposed label [outer (secondary) & inner (primary)] & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens

The submission against this point is optional.

1.5.12 Description of Batch numbering system

The submission against this point is optional.

1.5.13 Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).
The submission against this point is optional.

1.5.14 Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).
The submission against this point is optional.

1.5.15 – 1.5.20 Commitments
I / we hereby undertake that:

1.5.15 After registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.

1.5.16 We shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.

1.5.17 In case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.

1.5.18 We will follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. *(For drug products to be imported, this commitment must be submitted by manufacturer abroad as well).*

1.5.19 In case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.

1.5.20 We will perform process validation and stability studies till the assigned shelf life for the first three consecutive batches of commercial scale, stability study of at least one batch every year in accordance with the protocols and continue real time stability study till assigned shelf life of the applied product.

1.5.20 a) We will be responsible to change the brand name in case the name resembles with already approved / registered names.

b) We will be responsible to change the label design if it resembles with any of the previously registered drug.

I / We hereby undertake that the above given information is true and correct to the best of my / our knowledge and belief.

1.5.21 Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
The submission against this point is optional.

1.5.22 Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
The submission against this point is optional.

1.6 Miscellaneous Information
1.6.1 Information on Prior-related Applications
The submission against this point is optional.

1.6.2 Appendix

1.6.3 Electronic Review Package
The applicant shall submit electronic review package in CD / USB including Quality Overall Summary.

1.6.4 QIS (Quality Information Summary)
The submission against this point is optional

1.6.5 Drug Substance related Document including following:
a. Name and address of API manufacturer.
b. Approval of manufacturing facility of API by regulatory body of country and validity.
For applications of locally manufactured drug product(s), the one of the following documents shall be submitted.

i. Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin.
ii. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
iii. CEP certificate.

For applications of imported drug product(s), the submission against this point is not required.
c. Vendor qualification / audit is
□ Document based
□ Site inspection based
d. Reason for point c.

MODULE 2: (OVERVIEWS AND SUMMARIES)

2.3 Quality Overall Summary (QOS)

- The applicants of innovator drug products can submit QOS either as per WHO QOS-PD template or as per ICH template for consideration by the Registration Board.

- For drug products other than innovator's product, Quality Overall Summary (QOS) shall be provided in WHO QOS-PD Template or template provided below.

INTRODUCTION
Summary of product information:

Non-proprietary name(s) of the Drug Product	
Proprietary name(s) of the Drug Product	
International non-proprietary name(s) of the Drug Substance, including form (salt, hydrate, polymorph)	
Applicant name and address	
Dosage form	
Strength	
Route of administration	
Proposed indication(s)	

Primary Contact person responsible for this application	**Title:** **First name:** **Family Name:**
Contact person's job title	
Contact person's details	
Corresponding address	
Town/City/Country	
Contact person's email address	
Contact person's phone number	

Note: Provide contact details of the person who is responsible for this application and have all the technical and administrative details related to this application.

Other Introductory information:

Related dossiers (e.g. Drug Product(s) with the same Drug Substance(s) submitted to DRAP:

Brand Name	**Date of submission in DRAP**	**Drug Substance, strength, dosage form (eg. Abacavir (as sulphate) 300 mg tablets)**	**Drug Substance manufacturer (including address if same supplier as current dossier)**

Identify available literature references for the Drug Substance and Drug Product:

Publication(s)	**Monograph exists/does not exist/exists in other combination only**	**Most recent edition/volume consulted**
Drug substance status in pharmacopoeias:		
USP	**<e.g. Monograph exists>**	**<e.g. USP 42>**
BP	**<e.g. Monograph exists>**	**<e.g. BP 2019>**
Ph.Eur.	**<e.g. Monograph exists>**	**<e.g. Ph.Eur. 10.0>**
Ph.Int.	**<e.g. monograph exists>**	**<e.g. Ph.Int. 9th Edition 2019>**
Other (e.g. JP)	**<e.g. Monograph exists>**	**<e.g. JP 17th Edition>**
Drug product status in pharmacopoeias:		
USP	**<e.g. Monograph exists>**	**<e.g. USP 42>**
BP	**<e.g. Monograph exists>**	**<e.g. BP 2019>**
Ph.Int.	**<e.g. monograph exists>**	**<e.g. Ph.Int. 9th Edition 2019>**
Other (e.g. JP)	**<e.g. Monograph exists>**	**<e.g. JP 17th Edition>**
Other reference texts (e.g. public access reports): Mandatory for new drugs or drug products for which official monograph does not exist		
<e.g. WHOPARs, EPARs, FDA review, PMDA review report>	**<e.g. WHOPAR HAXXX>**	**<e.g. EMA PAR of June 2018>**

Do not delete any row in the above table. For drug products for which official monograph do not exist, the information regarding other references (e.g. public assessment reports) is mandatory to mention.

2.3.S Drug Substance

<For drug products having more than one drug substances, a separate section 2.3.S shall be provided for each drug substance >

2.3.S.1 General Information

2.3.S.1.1 Nomenclature

(a) (Recommended) International Non-proprietary name (INN):

(b) Compendial name, if relevant:

(c) Chemical name(s):

(d) Other non-proprietary name(s) (e.g. national name, USAN, BAN):

(e) Chemical Abstracts Service (CAS) registry number:

2.3.S.1.2 Structure

(a) Structural formula, including relative and absolute stereochemistry:

(b) Molecular formula:

(c) Relative molecular mass:

<For drug substance(s) existing as salts the molecular mass of the free base or acid shall also be provided>

2.3.S.1.3 General Properties

(a) Physical description (e.g. appearance, colour, physical state):

(b) Solubilities:

In common solvents:

Quantitative aqueous pH solubility profile (pH 1.2 to 6.8) at 37°C:

Medium (e.g. pH 4.5 buffer)	**Solubility (mg/ml)**
<pH = pKa, if pKa is between 1.2 and 6.8>	**<e.g. pKa = 13.1, therefore solubility result at this pH is not required>**

(c) Physical form (e.g. polymorphic form(s), solvate, hydrate):

Polymorphic form:

Solvate:

Hydrate:

(d) Other:

Property	
pH	
pK	
Partition coefficients	
Melting/boiling points	
Specific optical rotation (specify solvent)	
Refractive index (liquids)	
Hygroscopicity	
UV absorption maxima/molar absorptivity	

2.3.S.2 Manufacture

2.3.S.2.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing, storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address (including block(s)/unit(s))	Responsibility

(b) Approval of Drug Substance / Drug Manufacturing License (DML) / Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin:

<The copy of certificate shall be provided in Module-1 section 1.6.5(b)>

2.3.S.2.2 Description of Manufacturing Process and Process Controls

The submission against this point is optional.

2.3.S.2.3 Control of Materials

The submission against this point is optional.

2.3.S.2.4 Controls of Critical Steps and Intermediates

The submission against this point is optional.

2.3.S.2.5 Process Validation and/or Evaluation

The submission against this point is optional.

2.3.S.2.6 Manufacturing Process Development

The submission against this point is optional.

2.3.S.3 Characterization

2.3.S.3.1 Elucidation of Structure and other Characteristics

(a) List of studies performed (e.g. IR, UV, NMR, MS, elemental analysis) and conclusion from the studies (e.g. whether results support the proposed structure):

<For Drug substance(s) that are not described in an officially recognized pharmacopoeia, the studies carried out to elucidate and/or confirm the chemical structure normally include elemental analysis, infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR) and mass spectra (MS) studies>

<For Drug substance(s) that are described in an officially recognized pharmacopoeia, it is generally sufficient to provide copies of the IR spectrum>

(b) Discussion on the potential for isomerism and identification of stereochemistry (e.g. geometric isomerism, number of chiral centres and configurations):

<Generally applicable for those drug substance(s), for which isomerism may impact the quality, safety or efficacy of the drug product>

(c) Summary of studies performed to identify potential polymorphic forms (including solvates): <including identification of and data on the drug substance lot used in stability studies>

<Generally applicable for those drug substance(s), for which polymorphic form may impact the quality, safety or efficacy of the drug product>

(d) Summary of studies performed to identify the particle size distribution of the API: <including identification of and data on the drug substance lot used in stability studies>

<Generally applicable for those drug substances, for which particle size may impact the quality, safety or efficacy of the drug product>

2.3.S.3.2 Impurities

(a) Identification of potential and actual impurities arising from the synthesis, manufacture and/or degradation:

i. List of Drug Substance / API-related impurities (e.g. starting materials, by-products, intermediates, chiral impurities, degradation products), including chemical name, structure, origin and acceptable limits:

Drug Substance / API-related impurity (chemical name and compendial name)	**Structure**	**Origin**	**Acceptable limit / Acceptance criteria**

ii. List of process-related impurities (e.g. residual solvents, reagents):

Process-related impurity (compound name)	**Acceptable limit / Acceptance criteria**

2.3.S.4 Control of the Drug Substance

2.3.S.4.1 Specification

(a) Drug Substance specifications of the Drug Product manufacturer:

Standard (e.g. USP, BP, Ph.Int., Ph.Eur., JP, in-house)		
Specification reference number and version		
Test	**Acceptance criteria**	**Analytical procedure (Type/Source/Version)**
Description		
Identification		
Impurities		
Assay		
etc.		

Provide Drug Substance Specifications of the Drug Product manufacturer. Avoid deleting this table and inserting specifications table provided by the Drug Substance / API manufacturer.

2.3.S.4.2 Analytical Procedures

(a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing):

<Provide brief tabulated summary of analytical procedures instead of attaching detailed analytical methods of Drug Substance manufacturer>

Detailed analytical procedures shall be provided in Module 3 under section 3.2.S.4.2

2.3.S.4.3 Validation of Analytical Procedures

(a) Summary of the validation information (e.g. validation parameters and results):

<Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s)>

Detailed data of verification of analytical procedures shall be provided in Module 3 under section 3.2.S.4.3

2.3.S.4.4 Batch Analyses

<Provide summarized results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer >

<Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacturer shall also be submitted>

(a) Summary of batch analyses release results *of the Drug Product manufacturer* for relevant batches used during product development and stability studies:

Test	**Acceptance Criteria**	**Results**		
		<batch x>	**<batch y>**	**etc.**
Description				

Test	Acceptance Criteria	Results		
		<batch x>	<batch y>	etc.
Identification				
Impurities				
Assay				
etc.				

<A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)>

2.3.S.4.5 Justification of Specification

<A discussion shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria, and differences from the officially recognized compendial standard(s)>

2.3.S.5 Reference Standards or Materials

(a) CoA of primary / secondary reference standard including source and lot number:

<For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable>

2.3.S.6 Container Closure System

(a) Description of the container closure system(s) for the shipment and storage of the Drug Substance:

Packaging component	Materials of construction

2.3.S.7 Stability

2.3.S.7.1 Stability Summary and Conclusions

(a) Summary of accelerated and long-term stability study testing parameters:

Accelerated stability study				
Storage condition (◦C, % RH)	Batch number	Batch size	Container closure system	Completed testing intervals

Long term / Real time stability study				
Storage condition (◦C, % RH)	Batch number	Batch size	Container closure system	Completed testing intervals

(b) Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate):

Container closure system	**Storage conditions / Storage statement**	**Re-test period***

* indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile Drug Substance).

2.3.S.7.2 Post-approval Stability Protocol and Stability Commitment

The submission against this point is optional.

2.3.S.7.3 Stability Data

(a) Summary of the stability results observed for the accelerated and long-term studies:
The actual stability results shall be provided in *Module 3* section 3.2.S.7.3.

2.3.P Drug Product

2.3.P.1 Description and Composition of the Drug Product

(a) Description of the Drug Product:

<e.g The proposed XYZ 50-mg tablets are available as white, oval, film coated immediate release tablets, debossed with'50' on one side and a break line on the other side>

(b) Composition of the Drug Product:

i. Composition, i.e. list of all components of the Drug Product and their amounts on a per unit basis and percentage basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**	
		Quant. per unit or per mL	**%**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>			
Subtotal 1			
<complete with appropriate title e.g. Film-coating >			
Subtotal 2			
Total			

(c) Description of accompanying reconstitution diluent(s), if applicable:

<Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product>

(d) Type of container closure system used for the Drug Product and accompanying reconstitution diluent, if applicable:

<The container-closure used for the drug product (and accompanying reconstitution diluent, if applicable) shall be briefly described, with further details provided under 3.2.P.7 Container-closure system>

2.3.P.2 Pharmaceutical Development

2.3.P.2.1 Components of the Drug Product

2.3.P.2.1.1 Drug Substance

(a) Discussion of the:

i. compatibility of the Drug Substance(s) with excipients listed in 2.3.P.1:

<If the qualitative composition of the formulation is not similar to innovator / reference product, the drug-excipient compatibility studies shall be provided>

ii. key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product:

iii. for fixed-dose combinations, compatibility of Drug Substance(s) with each other:

<For combination products, which are not approved by any reference regulatory authority, the compatibility of drug substances with each other shall be discussed>

2.3.P.2.1.2 Excipients

(a) Discussion of the choice of excipients listed in 2.3.P.1, their concentrations and characteristics that can influence the Drug Product performance):

2.3.P.2.2 Drug Product

2.3.P.2.2.1 Formulation Development

(a) Summary describing the development of the Drug Product:

<Brief discussion on the formulation development procedure adopted for the currently applied Drug Product>

(b) Pharmaceutical equivalence:

<The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed>

For innovator drug products, the submission of pharmaceutical equivalence is not required.

i. Summary of the results of comparative dissolution profile (where applicable):

<The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 shall be submitted and discussed>
<For comparative dissolution profile, the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms - Dissolution Profile Comparisons may be followed>

For innovator drug products, the submission of comparative dissolution profile is not required.

2.3.P.2.2.2 Overages

(a) Justification of overages in the formulation(s) described in 2.3.P.1:

<Generally overages are not acceptable unless fully justified>

2.3.P.2.2.3 Physicochemical and Biological Properties

(a) Discussion of the parameters relevant to the performance of the Drug Product (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties):

2.3.P.2.3 Manufacturing Process Development

(a) Discussion of the development of the manufacturing process of the Drug Product (e.g. optimization of the process, selection of the method of sterilization):

<The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified>
<Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided.>
2.3.P.2.4 Container Closure System

(a) Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the Drug Product (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the Drug Product):

<A brief description of container closure shall be included>

(b) For a device accompanying a multi-dose container, a summary of the study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume for the lowest intended dose):

<e.g. for Dry Powder Inhalers supplied with rotacaps, the studies including uniformity of delivered dose, aerodynamic particle size distribution etc. shall be provided>

2.3.P.2.5 Microbiological Attributes

(a) Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies):

<Antimicrobial (preservative) effectiveness studies to be performed as per recommendations of pharmacopoeia>

2.3.P.2.6 Compatibility

(a) Discussion of the compatibility of the Drug Product (e.g. with reconstitution diluent(s) or dosage devices, co-administered Drug Product(s)):

<Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product>

2.3.P.3 Manufacture

2.3.P.3.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

Name and address (include block(s)/unit(s))	**Responsibility**

(b) Good Manufacturing Practices (GMP) certificate of all manufacturing sites mentioned above:

<For applications of locally manufactured drug products, GMP certificate of all sites shall be provided in Module 1>
<For applications of imported drug products, Certificate of Pharmaceutical Product or GMP certificate of all manufacturing sites shall be provided in Module 1>

2.3.P.3.2 Batch Formula

(a) List of all components of the Drug Product to be used in the manufacturing process and their amounts on a per batch basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard	**Quantity per batch**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>	
Subtotal 1	
<complete with appropriate title e.g. Film-coating >	
Subtotal 2	
Total	

2.3.P.3.3 Description of Manufacturing Process and Process Controls

(a) Flow diagram of the manufacturing process:

<A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified>
<The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified>

2.3.P.3.4 Controls of Critical Steps and Intermediates

(a) Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:

Step (e.g. granulation, compression, coating)	**Controls**	
	Tests	**Acceptance criteria**

<Tests and acceptance criteria of the critical steps identified in Description of Manufacturing Process and Process Controls shall be provided, to ensure that the process is controlled>

2.3.P.3.5 Process Validation and/or Evaluation

(a) Summary of the proposed process validation protocol for the critical steps or critical assays used in the manufacturing process:

<For applications of locally manufactured drug products, a brief description of process validation including the proposed protocol based upon the process steps and controls mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be described. It shall be noted that first three consecutive batches of commercial scale will be subjected to the process validation in accordance with the protocol>

<For applications of imported drug products, process validation reports including the protocols and results for critical process steps mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be provided>

2.3.P.4 Control of Excipients

<If the excipient(s) are in pharmacopoeia there is no need to provide detailed specifications or its analytical procedures. However for excipients of non-compendial standards, specifications as well as analytical procedures shall be provided>

2.3.P.4.1 Specifications

(a) Summary of the specifications for in-house standard excipients:

<The specifications for excipients of non-compendial standard shall be provided>

2.3.P.4.2 Analytical Procedures

(a) Summary of the analytical procedures for in-house standard excipients:

<Copies of analytical procedures of non-compendial excipient shall be submitted>

2.3.P.4.3 Validation of Analytical Procedures

(a) Summary of the validation information for the analytical procedures for in-house standard excipients:

2.3.P.4.4 Justification of Specifications

(a) Justification of the specifications for the analytical procedures for in-house standard excipients:

2.3.P.4.5 Excipients of Human or Animal Origin

<For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE>

2.3.P.4.6 Novel Excipients

<For excipient(s) used for the first time in a drug product or by a new route of administration, full details of specification and testing method shall be provided>

2.3.P.5 Control of Drug Product

2.3.P.5.1 Specification(s)

(a) Specification(s) for the Drug Product:

Standard (e.g. USP, BP, Ph.Int., JP, in-house)			
Specification reference number and version			
Test	**Acceptance criteria (release)**	**Acceptance criteria (shelf-life)**	**Analytical procedure (type/source/version)**
Description			
Identification			
Impurities			
Assay			
etc.			

<Specifications shall include the degradation products and related substances>

2.3.P.5.2 Analytical Procedures

(a) Summary of the analytical procedures (e.g. key method parameters, conditions, system suitability testing):

<Provide brief tabulated summary of analytical procedures including key method parameters and conditions instead of attaching detailed analytical methods of Drug Product>
Detailed analytical procedures shall be provided in Module 3 under section 3.2.P.5.2

2.3.P.5.3 Validation of Analytical Procedures

(a) Summary of the validation information (e.g. validation parameters and results):

<For in-house methods, analytical method validation shall be performed>

<All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy>
<Brief summary of validation / verification shall be provided here, instead of attaching detailed protocols and results of analytical method validation>

Summarized tabulated results of validation / verification shall be provided in 2.3.R.2.

2.3.P.5.4 Batch Analyses

(a) Description of the batches:

Batch number	**Batch size**	**Date of manufacturing**	**Use (e.g. pharmaceutical equivalence or stability)**

(b) Summary of batch analyses release results for relevant batches (e.g. comparative bioavailability or biowaiver, stability):

Test	**Acceptance criteria**	**Results**		
		<batch x>	**<batch y>**	**etc.**
Description				
Identification				
Impurities				
Assay				
etc.				

2.3.P.5.5 Characterization of Impurities

<Those impurities that are degradation product shall be included in the specifications>
2.3.P.5.6 Justification of Specification(s)

<The justification of specification(s) for non-pharmacopeial products must be provided. Justification of specification of non-pharmacopeial product shall be based on batch analysis results>

2.3.P.6 Reference Standards or Materials

(a) Specifications of primary / secondary reference standard including source and lot number for primary reference standards:
<For testing of Pharmacopeial Drug Product(s), the use of primary reference standard is recommended, however for non-pharmacopeial Drug Product(s), a secondary reference standard is acceptable>

2.3.P.7 Container Closure System

(b) Description of the primary container closure systems, including unit count or fill size, container size or volume:

Description of primary container closure (including materials of construction)	Unit count or fill size (e.g. 60s, 100s etc.)	Container size (e.g. 5 ml, 100 ml etc.)

2.3.P.8 Stability

2.3.P.8.1 Stability Summary and Conclusions

(a) Summary of accelerated and long-term stability study:

Accelerated stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

Long term / Real time stability study				
Storage condition (◦C, % RH)	**Batch number**	**Batch size**	**Container closure system**	**Completed testing intervals**

(b) Summary of additional stability studies (if applicable): *<e.g. in-use studies for drug products which are to be reconstituted before use>:*

(c) Proposed storage statement and shelf-life:

Container closure system	Storage statement	Shelf-life

(d) Proposed in-use storage statement and in-use shelf-life:

Storage statement	Shelf-life

All the data and statements provided in this section shall be based on ICH and WHO guidelines

2.3.P.8.2 Post-approval Stability Protocol and Stability Commitment

(a) Stability protocol for *Commitment batches* (e.g. storage conditions, batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	Details	
Storage condition(s) (◦C, % RH)		
Batch number(s) / batch size(s)	*<not less than three production batches in each container closure system>*	
Tests and acceptance criteria	Description	

Parameter	Details	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

<For applications of imported drug product(s) where stability study data till complete shelf life is submitted, post-approval stability protocols and commitment is not required>

2.3.P.8.3 Stability Data

(a) Conclusion of the stability studies:

The actual stability results shall be provided in Module 3 section 3.2.P.8.3

2.3.A Appendices

2.3.A.1 Facilities and Equipment

<Provide a list of manufacturing and testing facilities / equipment available with reference to the applied drug product>

2.3.A.2 Adventitious Agents Safety Evaluation

The submission against this point is optional.

2.3.A.3 Excipients

<For excipient(s) used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross references to supporting safety (non-clinical and/or clinical) data shall be provided>

2.3.R Regional Information

2.3.R.1 Production Documentation

2.3.R.1.1 Executed Production Documents

<Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>

2.3.R.1.2 Master Production Documents

<For applications of locally manufactured drug product(s), provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product>

<For applications of imported drug product(s) the submission of master production documents is not required>

2.3.R.2 Analytical Procedures and Validation Information for Drug Product

<Provide analytical method validation / verification results in the table below>

ANALYTICAL PROCEDURES AND VALIDATION INFORMATION SUMMARIES			
HPLC Method Summary		**Volume/Page:**	
Method name:			
Method code:		**Date:**	
Column(s) / temperature (if other than ambient):			
Mobile phase (specify gradient program, if applicable):			
Detector (and wavelength, if applicable):			
Flow rate:			
Injection volume:			
Sample solution preparation and concentration (expressed as mg/ml, let this be termed "A"):			
Reference solution preparation and concentration (expressed as mg/ml and as % of "A"):			
System suitability solution concentration (expressed as mg/ml and as % of "A"):			
System suitability tests (tests and acceptance criteria):			
Method of quantification (e.g. against API or impurity reference standard(s)):			

Validation Summary		**Volume/Page:**			
Analytes:					
Typical retention times (RT)					
Relative retention times ($RT_{Imp.}/RT_{API\ or\ Int.\ Std.}$):					
Relative response factor ($RF_{Imp.}/RF_{API}$):					
Specificity:					
Linearity / Range:	**Number of concentrations:** **Range (expressed as mg/ml and as % "A"):** **Slope:** **Y-intercept:** **Correlation coefficient (r^2) :**				
Accuracy:	**Conc.(s) (expressed as mg/ml and as % "A"):** **Number of replicates:** **Percent recovery (avg/RSD):**				
Precision / Repeatability: (intra-assay precision)	**Conc.(s) (expressed as mg/ml and as % "A"):** **Number of replicates:** **Result (avg/RSD):**				
Precision / Intermediate Precision: (days/analysts/equipment)	**Parameter(s) altered:** **Result (avg/RSD):**				
Limit of Detection (LOD): (expressed as mg/ml and as % "A")					
Limit of Quantitation (LOQ): (expressed as mg/ml and as % "A")					
Robustness:	**Stability of solutions:**				

	Other variables/effects:	
Typical chromatograms or spectra may be found in:		
Company(s) responsible for method validation:		

2.4 Non-Clinical Overview

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.4 is optional.

2.5 Clinical Overview

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.5 is optional.

2.6 Non-Clinical Written and Tabulated Summaries

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.6 is optional.

2.7 Clinical Summary

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in section 2.7 is optional.

4. MODULE 3: (QUALITY / CMC)

3.2.S Drug Substance

3.2.S.1 General Information

Nomenclature

Information on the nomenclature of the drug substance shall be provided. For example: INN, compendial name, USAN, BAN, CAS registry name where applicable.

Structure

The structural formula, including relative and absolute stereochemistry, the molecular formula, and the relative molecular mass shall be provided. For APIs existing as salts or esters the molecular mass of the free base or acid shall also be provided.

General Properties

The physical and chemical properties of the API shall be discussed, including the physical description, solubility in common solvents (e.g. water, alcohols, dichloromethane and acetone), quantitative aqueous pH solubility profile (e.g. pH 1.2–6.8, dose/solubility volume), polymorphism, pH and pKa values, ultraviolet (UV) absorption maxima and molar absorptivity, melting point, refractive index (for a liquid), hygroscopicity and partition coefficient.

This list is not intended to be exhaustive but provides an indication as to the type of information that could be included. Such information can be obtained either from the open part of drug master file or from manufacturer as well as from reference literature.

3.2.S.2 Manufacture

The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided. It is important that the site of the manufacturer as well as its role and responsibility with respect to manufacturing, packing and testing shall be clearly identified. The name and address of the site shall be given. If the manufacturing, processing, packaging or testing is performed by an outside contractor or third party contractor, this shall be clearly identified and copy of quality agreement shall be included.

A certificate of compliance with GMP shall be provided in the Module-1.

3.2.S.3 Characterization

Elucidation of Structure and other Characteristics

Drug substances /Active Pharmaceutical Ingredients that are not described in an officially recognized pharmacopoeia, the studies carried out to elucidate and/or confirm the chemical structure normally include elemental analysis, infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR) and mass spectra (MS) studies. Other tests could include X-ray powder diffraction (XRPD) and differential scanning calorimetry (DSC). Drug substance /Active Pharmaceutical Ingredients that are described in an officially recognized pharmacopoeia it is generally sufficient to provide copies of the IR spectrum.

Discussion on the potential for isomerism and identification of stereochemistry, studies performed to identify potential polymorphic forms and particle size distribution of the Drug substance shall be submitted, where these parameters may impact the quality, safety or efficacy of the drug product.

Impurities

List of Drug Substance / API-related impurities and process-related impurities shall be submitted along with acceptance limits.

3.2.S.4 Control of Drug Substance

Specification

Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.

Analytical procedures

Detailed analytical procedures for the testing of drug substance shall be provided.

Validation of analytical procedures

Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.

Batch analysis

Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.

A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).

Justification of specifications

A discussion/justification shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria. Any differences from the officially recognized compendial standard(s) shall also be justified.

3.2.S.5 Reference Standards or Materials

For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable.

COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.S.6 Container Closure System

Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component.

Other information on the container closure system(s) (e.g. suitability studies) may be submitted.

3.2.S.7 Stability

- The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted.
- For locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV a conditions.
- In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.
- Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.

3.2.P Drug Product

3.2.P.1 Description and Composition of the Drug Product

a) Description of the dosage form

The description of the Drug product shall include the physical description, available strengths, release mechanism (e.g. immediate or modified (delayed or extended)), as well as any other distinguishable characteristics, e.g.

"The proposed XYZ 50-mg tablets are available as white, oval, film coated tablets, debossed with '50' on one side and a break line on the other side.

b) Composition

List of all components of the dosage form, and their amount on a per unit basis (including overages*, if any), the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications).

* *Overages are not acceptable unless fully justified*

If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride").

c) **Description of accompanying reconstitution diluent(s)**

Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug.

d) Type of Container Closure:

The container-closure used for the Drug Product (and accompanying reconstitution diluent, if applicable) shall be briefly described, with further details provided under 3.2.P.7 Container-closure system

3.2.P.2 Pharmaceutical Development

A brief information on the pharmaceutical development shall be included. This information specify the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed.

Components of the Drug Product

Drug substance

Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product.

Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product.

For fixed-dose combinations, compatibility of Drug Substance(s) with each other shall be discussed, where in the applied formulation is not approved any reference regulatory authority.

Excipients

Discussion of the choice of excipients, their concentrations and characteristics that can influence the Drug Product performance shall be provided.

Formulation Development

a) A brief description of formulation development shall be given.
b) *Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.
c) Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 shall be submitted and discussed.
d) Justification of overages in the formulation(s) shall be submitted.
e) Discussion of the parameters relevant to the performance of the Drug Product (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties).

* For innovator drug products, the submission of pharmaceutical equivalence and comparative dissolution profile is not required.

Manufacturing Process Development

The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified.

Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided.

Container Closure System

Discussion of the suitability of the container closure system (described in 2.3.P.7) used for the storage, transportation (shipping) and use of the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP) shall be provided.

For a device accompanying a multi-dose container, study results demonstrating the reproducibility of the device (e.g. consistent delivery of the intended volume for the lowest intended dose) shall be submitted.

Microbiological Attributes

Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.

Compatibility

Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.

3.2.P.3 Manufacture

The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.

The list of manufacturers or companies shall specify the actual addresses of production or manufacturing site(s) involved (including block(s) and unit(s)), rather than the administrative offices. For applications of locally manufactured drugs, GMP certificate of all sites shall be provided. For applications of imported drugs, Certificate of Pharmaceutical Product or GMP certificate of all manufacturing sites shall be provided.

Batch formula

A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.

If the drug product is formulated using an active moiety, then the composition for the drug substance shall be clearly indicated (e.g. "1 kg of active ingredient base = 1.075 kg active ingredient hydrochloride").

Description of manufacturing process and process controls

A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified.
Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section.
The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified.

Controls of critical steps and intermediates

Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled.

Process validation and/or evaluation

For applications of locally manufactured drug products, a brief description of process validation including the proposed protocol shall be described. A commitment to perform process validation on first three consecutive batches of commercial scale shall be provided in Module-1.
For applications of imported drug products, process validation reports including the protocols and results for critical process steps mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be provided.

3.2.P.4 Control of Excipients

Specifications

The specifications for excipients shall be provided. If the excipient(s) are in pharmacopoeia there is no need to provide detailed specifications or its analytical procedures. However for excipients of non-compendial standards, specifications as well as analytical procedures shall be provided.
The colors permitted for use are limited to those listed in the FDA "Inactive ingredient guide", "Japanese pharmaceutical excipients" or the European Union (EU) "List of permitted food colors".
For proprietary mixtures, the composition sheet provided by the supplier shall be submitted.

Analytical procedures

Copies of analytical procedures of non-compendial excipient shall be submitted.

Validation of analytical procedures

Validation information for the analytical procedures for in-house standard excipients shall be submitted.

Justification of specifications

Justification of the specifications for the analytical procedures for in-house standard excipients shall be provided.

Excipients of Human or Animal Origin

For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE.

Novel Excipients

For excipient(s) used for the first time in a drug product or by a new route of administration, full details of specification and testing method shall be provided.

3.2.P.5 Control of Drug Product

Specification(s)

A copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure shall be provided. Specifications shall also include the details of impurities (as applicable).

Analytical procedures

Detailed analytical procedures used for testing the drug product shall be provided.

Validation of analytical procedures

For in-house methods, analytical method validation shall be performed.

All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy.

Batch analysis

The copies of complete analysis of at least two batches shall be provided.

Characterization of impurities

Those impurities that are degradation product shall be included in the specifications.

Justification of specifications

The justification of specification(s) for non-pharmacopeial products must be provided. Justification of specification of non-pharmacopeial product shall be based on batch analysis results.

3.2.P.6 Reference Standards or Materials

For testing of Pharmacopeial Drug Product(s), the use of primary reference standard is recommended, however for non-pharmacopeial Drug Product(s), a secondary reference standard is acceptable.
COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.P.7 Container Closure System

A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided.

3.2.P.8 Stability

For the pre-market authorization stability studies for a period of 6 months accelerated and real time in proposed container closure system is required in accordance with the Zone Iva conditions. Based on the satisfactory results, a two years shelf life will be granted. For selection of number and size of batches applicant may follow , any of the following options:

a) ICH/WHO guidelines.

b) At least 2 batches having the following minimum batch size considering the scientific reliability
- OSDs : 5000 Units
- Oral Liquid/Suspension : 2000
- Injectable : 2000
- Aerosol and any other specialized preparations : 500

c) At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life.

Stability summary and conclusion (Finished pharmaceutical product):

Summary of stability batches with details of storage conditions, batch numbers, batch size, testing intervals and container closure system along with proposed storage statement and shelf-life shall be provided.
Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

Post-approval Stability Protocol and Stability Commitment:

For applications of locally manufactured drug product(s), stability protocol for commitment batches (e.g. storage conditions, batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s) shall be provided. A written commitment (signed and dated) to continue long-term testing over the shelf-life shall be included in Module-1.
For applications of imported drug product(s) where stability study data till complete shelf life is submitted, post-approval stability protocols and commitment is not required.

Stability Data:

Results of the stability studies shall be presented in an appropriate format (provided below).
The actual stability results and reports used to support the proposed shelf-life shall be provided. For quantitative tests (e.g. individual and total degradation product tests and assay tests), actual numerical

results shall be provided rather than vague statements such as "within limits" or "conforms". Conduction of stability study data shall be scientifically justified.

Storage Conditions:

a) General case

The general case applies if the drug product is not specifically covered by any other storage condition in the subsequent sections.

Study	Storage condition
Accelerated	40°C ± 2°C / 75% RH ± 5% RH
Long term	30°C ± 2°C / 65% RH ± 5% RH

b) Drug products packaged in semi-permeable containers

Aqueous-based products packaged in semi-permeable containers shall be evaluated for potential water loss in addition to physical, chemical, biological, and microbiological stability.

Other comparable approaches can be developed and reported for non-aqueous, solvent-based products.

Study	Storage condition
Accelerated	40°C ± 2°C / NMT 25% RH
Long term	30°C ± 2°C / 35% RH ± 5% RH

c) Drug products intended for storage in a refrigerator

Study	Storage condition
Accelerated	25°C ± 2°C / 60% RH ± 5% RH
Long term	5°C ± 3°C

d) Drug products intended for storage in a freezer

Study	Storage condition
Accelerated	5°C ± 3°C or 25°C ± 2°C
Long term	- 20°C ± 5°C

Stability data submission:

- For applications of imported drug product(s), real time and accelerated stability data (summary sheets) as per ICH guidelines or till claimed shelf life as per the storage conditions mentioned above shall be provided.
- For applications of locally manufactured drug product(s), the stability study data shall be provided as per the below mentioned format.

Stability study data submission locally manufactured products for CTD:

<u>Stability Study Data Sheet</u>

Product details:

Product name	ABCD 100mg tablets		Batch No.	
Description of pack (container closure system)	e.g: Alu-Alu blister of 10's packed in printed unit carton, further packed in a master shipper.		Batch Size.	
Parameters and tests mentioned	As per Product Specifications		Mfg. Date	
Recommended storage conditions	Accelerated conditions		Exp Date	

	Real time conditions			
Date of initiation of stability studies			(API) lot no.	

Accelerated Stability study data:

Storage conditions				
Assessment frequency (Months)		Initial	3	6
Date of Testing				
Tests (as per specifications)	Acceptance Criteria			

Real time stability study data:

Storage conditions				
Assessment frequency (Months)		Initial	3	6
Date of Testing				
Tests (as per specifications)	Acceptance Criteria			

Documents / Data to be provided along with stability study data:

1.	Reference of previous approval of applications with stability study data of the firm (if any)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
3.	Documents for the procurement of API with approval from DRAP (in case of import).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

3.2.A Appendices

Facilities and equipment

A list of manufacturing and testing facilities / equipment available with reference to the applied drug product shall be provided.

Adventitious agent safety evaluation

The submission against this point is optional.

Excipients

For excipient(s) used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross references to supporting safety (non-clinical and/or clinical) data shall be provided.

3.2.R Regional Information

Production Documentation Human Blood product with required supporting documents:
The submission against this point is optional.

TSE Checklist with required supporting documents:
For excipients of human or animal origin, a certificate stating that all excipients used in the applied drug product, are free from BSE and TSE.

Product Interchangeability (Bioequivalence study reports):
The submission against this point is optional.

Blank production batch record:
For applications of locally manufactured drug product(s), provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product For applications of imported drug product(s) the submission of master production documents is not required.

Module 4: (Non-clinical / Safety)
For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 4 is optional.

Module 5: (Clinical / Efficacy)
For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 5 is optional.

Section/subsection wherein data submission is optional:
Registration Board decided that data requirements for following components / part of CTD will be optional.

Chemistry, Manufacturing and Control (CMC) data		
Sub-section of Drug substance	**Sub section in Module 2**	**Sub section in Module 3**
Description of Manufacturing Process and Process Controls	2.3.S.2.2	3.2.S.2.2
Control of Materials	2.3.S.2.3	3.2.S.2.3
Control of critical steps and Intermediates	2.3.S.2.4	3.2.S.2.4
Process Validation and/or Evaluation	2.3.S.2.5	3.2.S.2.5
Manufacturing Process Development	2.3.S.2.6	3.2.S.2.6
Post-approval Stability Protocol and Stability Commitment	2.3.S.7.2	3.2.S.7.2
Product Interchangeability (Bioequivalence Study Reports)	-	3.2.R.3

Non-Clinical and Clinical Data
Module / Section / Sub-section
Module 2.4 Non-Clinical Overview
Module 2.5 Clinical Overview
Module 2.6 Non-Clinical Written and Tabulated Summaries
Module 2.7 Clinical Summary
Module 4: (Non-clinical / Safety)
Module 5: (Clinical / Efficacy)

REFERENCES

1. The DRAP Act, 2012.
2. The Drugs Act 1976.
3. The Drugs (Licensing, Registering and Advertising) Rules, 1976.
4. Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part (Annex 6 of WHO Technical Report Series No. 986, 2014).
5. ICH -M4Q (R1) Guidelines.
6. WHO QUALITY OVERALL SUMMARY: PRODUCT DOSSIER (QOS-PD) TEMPLATE

DRUG REGULATORY AUTHORITY OF PAKISTAN
Telecom Foundation Complex, G-9/4, Islamabad, Pakistan
Email: addl-dir.pe.reg@dra.gov.pk Phone:92-51-9107416
www.dra.gov.pk

Registration applications with stability study data

Case no. 01 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
1.	M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar.	Empaa-M XR 25 mg/1000mg Tablet Each film coated Extended Release tablet contains Empagliflozin……..25mg Metformin Hydrochloride…….1000mg **Sodium Glucose Co transporter 2 Inhibitors, Biguanides** (Manufacturers specifications)	Form-5D Dy.No.4876; 04-02-2019; Rs.50,000/- 04-02-2019 As per SRO As per SRO	Synjardy Xr tablet of USFDA approved Last inspection conducted on 15-09-2017 and report concludes that Overall the firm was GMP Compliant	

1. **STABILITY STUDY DATA**

Drug	Empaa-M XR 25 mg/1000mg Tablet			
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar.			
Manufacturer of API	Empagliflozin	M/s Zhejiang Hongyuan Pharmaceuticals co ., Ltd		
	Metformin Hydrochloride	M/s IOL Chemicals and Pharmaceuticals		
API Lot No.	Empagliflozin	20180515		
	Metformin Hydrochloride	4250/1203/18/A-0184PM		
Description of Pack (Container closure system)	Alu Blister			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0,1,2 3,4,6 (month) Real Time: 0,3 ,6 (month)			
Batch No.	T- 31	T- 32	T- 33	
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet	
Manufacturing Date	14-08-2018	14-08-2018	14-08-2018	
Date of Initiation	16-08- 2018	16-08- 2018	16-08- 2018	
No. of Batches	3			
Date of Submission	15-04-2019 (Dy. No. 3606)			

2. **DOCUMENTS / DATA PROVIDED BY THE APPLICANT**			
Sr.	**Documents To Be Provided**	**Status**	
1.	COA of API	Empagliflozin	Copy of COA by M/s Zhejiang Hongyuan Pharmaceuticals co ., Ltd Limited is submitted.
		Metformin Hydrochloride	Copy of COA by M/s IOL Chemicals and Pharmaceuticals Limited is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Empagliflozin	Copy of GMP Certificate No. ZJ20180032 by China Food and Drug Adminstration valid till 03-14-2023.
		Metformin Hydrochloride	Copy of GMP Certificate No. Drugs (7) Pb.2018/ 1895 by Food & Drug Administration Punjab valid till 07-03-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes	
5.	Documents confirming import of API etc.	Empagliflozin	Copy of Commercial Invoice No 10053012 Dated: 11-07-2018 is submitted attested by ADC(Peshawar) dated ;19-07-2018.
		Metformin Hydrochloride	Copy of Commercial Invoice No TM/104/18-19 Dated: 17-01-2018 by The molecules, Mumbai India is submitted. But not ADC attested
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes	
8.	Commitment to follow Drug Specification Rules, 1978.	Yes	

9. REMARKS OF EVALUATOR

The panel may be requested to verify and report about following points in addition to authenticity of stability data and associated documents,

- Import of metformin because Form 3, Form 7 and goods declaration for metformin attached but commercial invoice not ADC attested.
- Applied technology of Active coating for Empagliflozin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride.
- 5% overage of Empagliflozin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that Empagliflozin overage was inducted due to drug loss during spray coating process and to attain the satisfactory contents of Empagliflozin as per claim.
- Method development study to justify that the result of dissolution analysis for metformin as performed by UV method have not been interfered with the ingredients of formulation specially the other API i.e Empagliflozin present in the same sample aliquote.

INSPECTION REPORT VERIFICATION OF AUTHENTICITY OF STABILITY DATA
M/s Weather folds Pharmaceuticals Plot 69. Phase II Industrial Estate Hattar

Inspection dated 01-09-2020 in compliance to DRAP PEC letter No.F.13-11/22017-PEC (Vol.1) dated 24-06-2020

Q.No.1	Do you have documents confirming the import of APIs?	APIs used were imported/locally purchased for already registered drugs) Empa: DRAP attested Invoice #1312 dated 19-7-2020 Metformin: GD copy available
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	Already available with the firm, GMP compliant and easy availability.
Q.No.3	Do you have documents confirming the import of Metformin and Empagliflozin reference standard and impurity standards?	Record unavailable for reference standard impurities.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes for API, Impurities not available
Q.No.5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	GMP certificates for both APIs available
Q.No.6	Do you use API manufacturer method of testing?	Yes
Q.No.7	Do you have stability studies reports on API?	Yes as supplied by manufacturer
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes
Q.No.9	Do you have method for quantifying the impurities in the API?	Only method available
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes for API, No for impurities reference standard.
Q.No.11	Have you used pharmaceutical grade excipients?	Yes
Q.No.12	Do you have documents confirming the import of the used excipients?	Locally purchased
Q.No.13	Do you have test reports and other records on the excipients used?	Yes
Q.No.14	Do you have written and authorized protocols for the development **Tablets**?	Yes
Q.No.15	Have you performed Drug-excipients compatibility studies?	Not performed.
Q.No.16	Whether firm has performed comparative dissolution studies?	Not performed.
Q.No.17	Do you have product development (R&D) section	**No**
Q.No.18	Do you have necessary equipments available in product development section for development **Tablets?**	Not Applicable
Q.No.19	Are the equipments in product development section qualified?	Not Applicable
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Not Applicable
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes
Q.No.22	Have you manufactured three stability batches for the stability studies **Tablets** as required?	Yes
Q.No.23	What was the criteria for fixing the batch size of stability batches?	Criteria for fixing batch size of stability batches is number of tablets per testing and number of testing frequencies according to 276th DRB meeting.
Q.No.24	Do you have complete record of production of stability batches?	Yes

Q.No.25	Do you have protocols for stability testing of stability batches?	Yes
Q.No.26	Do you have developed and validated the method for testing of stability batches?	In-house method developed and validated
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Calibration record maintained.
Q.No.29	Do your method of analysis stability indicating?	Yes, method validated
Q.No.30	Do your HPLC software is 21CFR compliant?	Yes, Empower2, waters , 600 series
Q.No.31	Can you show Audit Trail reports on **Empaa-XR Tablets** testing?	Yes
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Degradation products not available Stability batches available
Q.No.33	Do you have commitment batches kept on stability testing?	Yes
Q.No.34	Do you have valid calibration status for the equipments used in **Empaa-XR Tablets** production in analysis?	Yes
Q.NO.35	Do proper and continuous monitoring and control are available for stability chamber?	21CFR compliant chambers have been provided with continuous power supply(power backup up to 12hrs) and digital data loggers with record of test period.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

- Only Good Declaration copy is available regarding import of Metformin.
- Empagliflozin is coated as solution on core of Metformin as confirmed from record during inspection.
- The firm production in-charge during inspection informed that overage of 5% was added to compensate for drug loss during manufacturing process.
- The firm has informed that they have developed and validated there method of analysis, record seen and found satisfactory.

Conclusion:

a. On risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of **Empaa-M XR Tablets (Empagliflozin 25mg, and Metformin 1000mg) Extended release tablets** is verifiable as per above mentioned details.

- Dr Abdul Rasheed, Director PS
- Atiq ul Bari, FID, Peshawar

Decision: Registration Board decided to approve registration of "Empaa-M XR 25 mg/1000mg Tablet by M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar. Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

b. Exemption from onsite verification of stability data

Deferred case:

2.	Name and address of manufacturer / Applicant	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi
	Brand Name +Dosage Form + Strength	Fludip 5 mg tablet
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin……....5mg
	Diary No. Date of R& I & fee	Dy.No 218 dated 09-09-2014 Rs. 50,000/- 08-09-2014

	Pharmacological Group	**Sodium Glucose Co-transporter 2 Inhibitors**
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 20's, & 30's:As per SRO
	Approval status of product in Reference Regulator Authorities	Farxiga 5mg tablet of USFDA approved
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA

Drug	Fludip 5 mg		
Name of Manufacturer	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi		
Manufacturer of API	M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China		
API Lot No.	DPG-201803001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6, 9 (month)		
Batch No.	19SB-201-01	19SB-202-02	19SB-203-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	21-01-2019	21-01-2019	21-01-2019
No. of Batches	03		
Date of Submission	16-01-2020 (30567)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
25.	COA of API.	Copy of COA (Batch# DPG-201803001) from M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China is submitted.
26.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.

27.	Protocols followed for conduction of stability study and details of tests.	Yes
28.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
29.	Documents confirming import of API etc.	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
30.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
31.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
32.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Wymly 25mg Tablet in its 281st Meeting. • Date of Inspection: 09-04-2018 • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
22.	Documents for the procurement of reference standard and impurity standards.	Firm have submitted letter from an indentor Neon chemicals and supplier is M/S Jiangsu Yongan pharmaceuticals Co., Ltd, China
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
24.	Mechanism for Vendor pre-qualification	The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.

<table>
<tr><td>25.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted
COA of API: Batch No. DPG-201803001
COA of Reference Standard: Batch No. DPG-201804001</td></tr>
<tr><td>26.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of all the excipients used in the formulation of applied product.</td></tr>
<tr><td>27.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing & stabilities studies</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table><tr><td colspan="3">Fludip 5 mg</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>19SB-201-01</td><td>1500 tablets</td><td>01-2019</td></tr><tr><td>19SB-202-02</td><td>1500 tablets</td><td>01-2019</td></tr><tr><td>19SB-203-03</td><td>1500 tablets</td><td>01-2019</td></tr></table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches. The detail is as under:
<table><tr><td>Batch No.</td><td>Stability samples</td><td>Qty used</td><td>Remaining Qty in Chamber</td></tr><tr><td>19SB-201-01</td><td>440</td><td>320</td><td>120</td></tr><tr><td>19SB-202-02</td><td>440</td><td>320</td><td>120</td></tr><tr><td>19SB-203-03</td><td>440</td><td>320</td><td>120</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 01-01-2019 to 31-10-2019 and for Real Time stability chamber starting from 01-01-2019 to 31-10-2019</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA. Analysis date:11-05-2018</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months</td></tr>
</table>

<table>
<tr><td></td><td></td><td>(30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>36.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that we manufactured lab scale batches of our applied products “Flucid 5mg” by using same formulation (excipients) of Innovator’s Product.</td></tr>
<tr><td>37.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator’s Brand “Forxiga Tablets” The details are as follows:
<table>
<tr><td>Feature</td><td>Reference. Product</td><td>Product Genix</td></tr>
<tr><td>Brand Name</td><td>Forxiga 5mg Tablet</td><td>Flucid 5mg</td></tr>
<tr><td>Batch No.</td><td>NJ535</td><td>19SB-201-01</td></tr>
<tr><td>Mfg. Date</td><td>03/2017</td><td>01-2019</td></tr>
<tr><td>Exp. Date</td><td>02/2020</td><td>01-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
4. Ph 1.2 HCl buffer
5. Ph 4.5 Acetate buffer
6. Ph 6.8 Phosphate buffer
Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies</td></tr>
<tr><td>38.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for complete stability studies analysis of three batches</td></tr>
</table>

Remarks of Evaluator:

S.No	Shortcoming communicated	Reply of Firm
1.	The firm has claimed that they manufactured lab scale batches of their applied product “Flucid 5mg” by using same formulation (excipients) of Innovator’s Product however yellow colour added in core. Clarify.	Firm reply that they are adding colour in very minute quantity in core formulation for segregation of product to avoid mixing as they have different products on same tooling in order to comply GMP.
2.	Innovator used dry granulation method while applied product is manufactured by direct compression . Justify.	Direct compression and dry granulation methods are almost same processes except unit operation that is compaction involve in dry granulation, while in both processes, formulation developed without using any solvent or liquid solution
3.	Submit Real time Stability of API according to zone IV -A	Stability studies of 3batches according to Zone IV-A submitted.
4.	Chromatograms for Content uniformity and dissolution testing at initial testing for Batch No: 19SB-201-01and chromatograms at initial dissolution testing Batch no: 19SB-201-03 not submitted	Submitted.

5.	Evidence of procurement of reference product	submitted
6.	**Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements for Q at 15 minutes**	• Firm reply that they are following FDA dissolution method. Dissolution time is 30 minutes mentioned. • On the basis of CDP data, the results were found above the 85% in 15 minutes • The dissolution test were conducted again at 15 minutes. The results were found above 80%(Q) = 85% • The dissolution results of all 3 batches are attached for the reference. • The specifications are revised for 15 minutes of dissolution testing.

Previous Decision(M-295)
Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

- Firm submitted reply that they had initially conducted dissolution studies at 15 minutes and 30 minutes on initially manufactured batch and Q of both 15 minutes and 30minutes testing is greater than 85%. They submitted the data for 2 batches at initial and one month time point at both **accelerated and real time stability conditions where the rest of test values are same but dissolution results are change from 30 minutes data.**
- **However at initially they submitted protocol in which they did not mentioned that the dissolution studies are conducted parallel at both 30 minutes and 15 minutes.**
- **When communicated through letter** No. F.1-1/2019/PEC-DRAP (AD PEC-IV*)* Dated: 30-06-2020 about **Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements for Q at 15 minutes. They did not mentioned that the dissolution studies are conducted parallel at both 30minutes and 15 minutes and replied that they were following FDA dissolution method where dissolution time is 30minutes and submitted results of one time dissolution testing on each batch i.e 19SB-201-01, 19SB-202-02 & 19SB-203-03 at 15 minutes.**

3.	Name and address of manufacturer / Applicant	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi
	Brand Name +Dosage Form + Strength	Fludip 10 mg
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin……....10mg
	Diary No. Date of R& I & fee	Dy.No 219 dated 09-09-2014 Rs. 50,000/- 08-09-2014
	Pharmacological Group	**Sodium Glucose Co-transporter 2 Inhibitors**
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 20's, & 30's:As per SRO
	Approval status of product in Reference Regulator Authorities	Farxiga 10mg tablet of USFDA approved

	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA			
Drug	Fludip 10 mg		
Name of Manufacturer	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi		
Manufacturer of API	M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China		
API Lot No.	DPG-201803001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6, 9 (month)		
Batch No.	19SB-204-01	19SB-205-02	19SB-206-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	24-01-2019	24-01-2019	24-01-2019
No. of Batches	03		
Date of Submission	16-01-2020 (30567)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# DPG-201803001) from M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Wymly 25mg Tablet in its 281st Meeting. • Date of Inspection: 09-04-2018 • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have submitted letter from an indentor Neon chemicals and supplier is M/S Jiangsu Yongan pharmaceuticals Co., Ltd, China
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
5.	Mechanism for Vendor pre-qualification	The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.
6.	Certificate of analysis of the API, reference standards and impurity standards	The firm has submitted COA of API: Batch No. DPG-201803001 COA of Reference Standard: Batch No. DPG-201804001
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of all the excipients used in the formulation of applied product.

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
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<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that we manufactured lab scale batches of our applied products “Flucid 5mg” by using same formulation (excipients) of Innovator’s Product.</td></tr>
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<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator’s Brand “Forxiga Tablets” The details are as follows:
<table>
<tr><td>Feature</td><td>Reference. Product</td><td>Product Genix</td></tr>
<tr><td>Brand Name</td><td>Forxiga 10mg Tablet</td><td>Flucid 10mg</td></tr>
<tr><td>Batch No.</td><td>AAP0252</td><td>19SB-204-01</td></tr>
<tr><td>Mfg. Date</td><td>10/2016</td><td>01-2019</td></tr>
<tr><td>Exp. Date</td><td>09/2019</td><td>01-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
7. Ph 1.2 HCl buffer
8. Ph 4.5 Acetate buffer
9. Ph 6.8 Phosphate buffer
Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for complete stability studies analysis of three batches</td></tr>
</table>

Remarks of Evaluator:

S.No	Shortcoming communicated	Reply of firm
1.	The firm has claimed that they manufactured lab scale batches of their applied product “Flucid 10mg” by using same formulation (excipients) of Innovator’s Product however yellow color added in core. Clarify.	Firm reply that they are adding color in very minute quantity in core formulation for segregation of product to avoid mixing as they have different products on same tooling in order to comply GMP.
2.	Innovator used dry granulation method while applied product is manufactured by direct compression . Justify.	Direct compression and dry granulation methods are almost same processes except unit operation that is compaction involve in dry granulation, while in both processes, formulation developed without using any solvent or liquid solution
3.	Submit Real time Stability of API according to zone IV -A	Stability studies of 3batches according to Zone IV-A submitted.
4.	Evidence of procurement of reference product	submitted
5.	**Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as “Shall comply with requirements for Q at 15 minutes.**	• Firm reply that they are following FDA dissolution method. Dissolution time is 30 minutes mentioned. • On the basis of CDP data, the results were found above the 85% in 15 minutes • The dissolution test were conducted again at 15 minutes. The results were found above 80%(Q) = 85% • The dissolution results of all 3 batches are attached for the reference.

		• The specifications are revised for 15 minutes of dissolution testing.

Previous Decision(M-295)

Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

- Firm submitted reply that they had initially conducted dissolution studies at 15 minutes and 30 minutes on initially manufactured batch and Q of both 15 minutes and 30minutes testing is greater than 85%. They submitted the data for 2 batches at initial and one month time point at both **accelerated and real time stability conditions where the rest of test values are same but dissolution results are change from 30 minutes data.**
- **However at initially they submitted protocol in which they did not mentioned that the dissolution studies are conducted parallel at both 30 minutes and 15 minutes.**
- **When communicated through letter** No. F.1-1/2019/PEC-DRAP (AD PEC-IV*)* Dated: 30-06-2020 about **Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements for Q at 15 minutes. They did not mentioned that the dissolution studies are conducted parallel at both 30minutes and 15 minutes and replied that they were following FDA dissolution method where dissolution time is 30minutes and submitted results of one time dissolution testing on each batch i.e 19SB-204-01, 19SB-205-02 & 19SB-206-03 at 15 minutes**

Decision: Registration Board decided to approve registration of "Fludip 10 mg tablet (Dapagliflozin as propanediol monohydrate) & Fludip 5 mg tablet (Dapagliflozin as propanediol monohydrate) by M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sundar industrial Estate, Raiwind Road, Lahore was granted New DML.

Following applications are submitted.

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sundar industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sunder Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18344, 27-07-2020
	Details of fee submitted	PKR 20,000/-: 05-05-2020

	The proposed proprietary name / brand name	**Pacisal-NS IV Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride ……. 900mg
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Electrolyte (B05XA03)
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Medisol NS 0.9% 500ml of Mediapk Ltd., (Reg.# 008242)
	GMP status of the Finished product manufacturer	New DML issued on 24-06-2019
	Name and address of API manufacturer.	M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, New Zeland.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative studies against the "Medisol 0.9% infusion".	

STABILITY STUDY DATA

Manufacturer of API	M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, New Zeland.		
API Lot No.	08012019		
Description of Pack (Container closure system)	Low Density Polyethylene film bags.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / NMT 25% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SO011100	SO021100	SO031100
Batch Size	4000 liters	4000 liters	4000 liters
Manufacturing Date	11-2019	11-2019	11-2019
No. of Batches	03		

Details of Documents submitted

1.	Reference of previous approval of applications with stability study data of the firm (if any)	--

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, NewZeland valid upto 29-03-2021 issued by Ministry of Health, Newzeland.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (Invoice#. SAB/1834) dated 07-10-2019 specifying the quantity of 375Kg of Sodium chloride. Supplier's details are as "Sabcon Chemicals, Karachi." Invoice is not attested by the DRAP office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
	Remarks of Evaluator[II]: Firm has submitted stability studies of drug substance for long term conditions i.e., 30˚C ± 2˚C / 75% ± 5%RH for 18 months.	
Decision: Deferred for clarification regarding import of API since submitted invoice does not reflect the name of the API manufacturer.		

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sundar industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sunder Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18341, 27-07-2020
	Details of fee submitted	PKR 20,000/-: 05-05-2020
	The proposed proprietary name / brand name	**Pacisal-NS IV Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium chloride ……. 900mg
	Pharmaceutical form of applied drug	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Electrolyte (B05XA03)
	Reference to Finished product specifications	USP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Medisol NS 0.9% 1000ml` of Mediapk Ltd., (Reg.# 008242)
	GMP status of the Finished product manufacturer	New DML issued on 24-06-2019
	Name and address of API manufacturer.	M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, New Zeland.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III (Drug Product):	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol, Finished product analytical method validation report & stability studies data.
	Remarks: Firm has performed comparative studies against the "Medisol 0.9% infusion".	

STABILITY STUDY DATA

Manufacturer of API	M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, New Zeland.		
API Lot No.	08012019		
Description of Pack Container closure system)	Low Density Polyethylene film bags.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / NMT 25% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	SL011100	SL021100	SL031100
Batch Size	4000 liters	4000 liters	4000 liters
Manufacturing Date	11-2019	11-2019	11-2019
No. of Batches	03		

Details of documents

1.	Reference of previous approval of applications with stability study data of the firm (if any)	--
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Dominion Salt Ltd., 89, totara street, Mount Maunganui, NewZeland valid upto 29-03-2021 issued by Ministry of Health, Newzeland.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (Invoice#. SAB/1834) dated 07-10-2019 specifying the quantity of 375Kg of Sodium chloride. Supplier's details are as "Sabcon Chemicals, Karachi." Invoice is not attested by the DRAP office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]: Firm has submitted stability studies of drug substance for long term conditions i.e., 30°C ± 2°C / 75% ± 5%RH for 18 months.		
Decision: Deferred for clarification regarding import of API since submitted invoice does not reflect the name of the API manufacturer.		

Case no. 03 Applications on Form 5F

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.
	Name, address of Manufacturing site.	**M/s** Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.# 15439 dated 23-08-2019
	Details of fee submitted	Rs. 20,000/- vide deposit slip# 1960609 dated 06-08-2019
	The proposed proprietary name / brand name	Empaglif 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. 10mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic agent ATC code: A10BK03
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by USFDA

	For generic drugs (me-too status)	Product: Xenglu tablet Manufacturer: Hilton pharma., Karachi.
	Name and address of API manufacturer.	M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China
	GMP status of the API manufacturer	Copy of GMP certificate (Certificate# JS20170734) valid upto 25-12-2022 issued by China Food & Drug Administration.
	GMP status of the FPP manufacturer	cGMP certificate valid upto 22-04-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III:	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution profile of applied product against the reference product, Jardiance (batch# 844574 in three buffers i.e., pH 1.2, pH 4.5 & pH 6.8.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Remarks of Evaluator:	

STABILITY STUDY DATA

Name of manufacturer	M/s Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.		
Name of Product	Empaglif 10mg Tablet		
Manufacturer of API	M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Jiangsu, China.		
API Lot No.	EGF20180801		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EMT-001	EMT-002	EMT-003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	11-2018	11-2018	11-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (JS20140321) valid upto 18-08-2019, issued by Jiangsu Food & Drug Administration for M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Jiangsu, China.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of invoice (invoice# PSPW-180904) cleared by DRAP Islamabad office dated 27-09-2018 specifying import of 0.5kg Empagliflozin.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REMARKS OF EVALUATOR		

7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s** Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.
	Name, address of Manufacturing site.	**M/s** Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.# 15440 dated 23-08-2019

	Details of fee submitted	Rs. 20,000/- vide deposit slip# 1960609 dated 06-08-2019
	The proposed proprietary name / brand name	Empaglif 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. 25mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Anti-diabetic agent ATC code: A10BK03
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	Product: Xenglu tablet Manufacturer: Hilton pharma., Karachi.
	Name and address of API manufacturer.	M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China
	GMP status of the API manufacturer	Copy of GMP certificate (Certificate# JS20170734) valid upto 25-12-2022 issued by China Food & Drug Administration.
	GMP status of the FPP manufacturer	cGMP certificate valid upto 22-04-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module-III:	Firm has submitted relevant information against the Module III, including Comparative Dissolution Profile studies, Process validation protocol and Finished product analytical method validation report.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted comparative dissolution profile of applied product against the reference product, Jardiance (batch# 744305 in three buffers i.e., pH 1.2, pH 4.5 & pH 6.8.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Remarks of Evaluator:	

STABILITY STUDY DATA	
Name of manufacturer	M/s Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan.
Name of Product	Empaglif 10mg Tablet
Manufacturer of API	M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Jiangsu, China.
API Lot No.	EGF20180801

Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EMT-004	EMT-005	EMT-006
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	11-2018	11-2018	11-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (JS20140321) valid upto 18-08-2019, issued by Jiangsu Food & Drug Administration for M/s. Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Jiangsu, China.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of invoice (invoice# PSPW-180904) cleared by DRAP Islamabad office dated 27-09-2018 specifying import of 0.5kg Empagliflozin.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Report on investigation of authenticity / genuineness of data submitted for registration of Empagliflozin 10mg & 25mg Tablet by M/s. Bio-Labs (Pvt) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad.

Composition of Panel:

- Dr. Qurban Ali, Member Registration Board.
- Mrs. Tehreem Sara, Deputy Director RRR, PE&R Division, DRAP Islamabad.
- Hafiz M. Ali Tayyab, Assistant Director Registration-II, PE&R Division, DRAP, Islamabad.

<table>
<tr><th>Sr. No.</th><th>Question</th><th>i. Observation by panel</th></tr>
<tr><td>1.</td><td>Do you have documents confirming the import of API including approval from DRAP?</td><td>Firm has imported 0.500Kg Empagliflozin from M/S Shanghai Pharma Group Changzhou Kony Phramaceuticals Co. Ltd., Daixi street, Luoyang Town, Wujin District, Changzhou, Jiangsu 213105, China. ADC clearance: 27/09/2018.</td></tr>
<tr><td>2.</td><td>What was the rationale behind selecting the particular manufacturer of API?</td><td>Vendor is selected on GMP status of firm, DMF and stability study data provided by API manufacture.</td></tr>
<tr><td>3.</td><td>Do you have documents confirming the import reference standard and impurity standards?</td><td>Firm has received working standard and impurity standards from their supplier Shanghai Pharma Group Changzhou Kony Phramaceuticals Co. Ltd., Daixi street, Luoyang Town, Wujin District, Changzhou, Jiangsu 213105, China confirming supply of following:
<table>
<tr><td>Particular</td><td>Quantity supplied</td></tr>
<tr><td>working standard</td><td>100mg</td></tr>
<tr><td>Impurity Standard A</td><td>10mg</td></tr>
<tr><td>Impurity Standard B</td><td>10mg</td></tr>
<tr><td>Impurity Standard C</td><td>Not imported</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Do you have certificate of Analysis of the API, reference standards and impurity standards?</td><td>Firm has COA of API and impurity standards A & B. COA of Impurity Standard C not available.</td></tr>
<tr><td>5.</td><td>Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>Firm has GMP certificate of Shanghai Pharma Group Changzhou Kony Phramaceuticals Co. Ltd., issued by CFDA, China. GMP certificate bears names of APIs manufactured by the firm but Empagliflozin was not included in that list as list on GMP certificate revised after every 5 years and validity of GMP certificate was also 5 years.</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer method of testing?</td><td>The firm has used API manufacturer method of testing.</td></tr>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>The firm has API stabilities reports conducted by API manufacturer.</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>Degradation products have not been quantified.</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>Firm has manufacturer method for quantifying impurities of API. No impurity was quantified while manufacturer has identified impurity A.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>Firm has remaining quantity of 200gm of API.
Small quantity of working standard is present.
Impurity standards not present</td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>Pharmaceutical grade excipient used as by Innovator (Lactose, Microcrystalline cellulose, Hydroxy propyl cellulose, Cross carmellose sodium, Colloidal Silicon dioxide, Magnesium stearate).</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Firm has necessary documents for import of used excipients.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>Firm has performed following tests of Excipients
Appearance
Solubility
Identification</td></tr>
</table>

<table>
<tr><td></td><td></td><td>pH
LOD
Panel advised the firm to improve Microbial testing along with data presentation.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development?</td><td>Product development protocol is available for Empaglif Tablets.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>Same excipients are used as by Innovator “Jardiance”, so drug excipient compatibility study was not performed.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Comparative dissolution studies have been performed against innovator product Jardiance, manufactured by Boehringer Ingelheim.
<table>
<tr><td>Detail</td><td>Test product</td><td>Reference product</td></tr>
<tr><td>Brand</td><td>Empaglif 10mg Tab</td><td>Jardiance 10mg Tab</td></tr>
<tr><td>Batch No</td><td>EMT-001</td><td>844574</td></tr>
<tr><td>Medium</td><td colspan="2">0.1 HCl, Acetate buffer, Phosphate buffer</td></tr>
</table>
<table>
<tr><td>Detail</td><td>Test product</td><td>Reference product</td></tr>
<tr><td>Brand</td><td>Empaglif 25mg Tab</td><td>Jardiance 25mg Tab</td></tr>
<tr><td>Batch No</td><td>EMT-004</td><td>744305</td></tr>
<tr><td>Medium</td><td colspan="2">0.1 HCl, Acetate buffer, Phosphate buffer</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>Firm has dedicated product development section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment’s available in product development section for development of new product?</td><td>Firm has equipment available in R&D section.
For wet mixing not equipment was available in R&D section.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>Equipment used in product development are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>Annual calibration program is available.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Firm has qualified staff in product development section.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of new product as required?</td><td>Firm has manufactured 03 stability batches (EMT-001, EMT -002, EMT -003) for Empaglif 10mg and (EMT -004, EMT -005, EMT -006) for Empaglif 25mg having batch size of 1500 Tablets.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>Criteria for fixing batch size is number of test required and testing frequency.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Complete record of production of stability batches for Empaglif 10mg & 25mg Tablets available.</td></tr>
</table>

25.	Do you have protocols for stability testing of stability batches?	Product testing protocol available for Empaglif Tablets.
26.	Do you have developed and validated the method for testing of stability batches?	Firm has performed following steps of validation; Precision Accuracy Linearity Ruggedness
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Equipment used in testing are qualified.
29.	Do your method of analysis stability indicating?	**Degradation products have not been quantified.**
30.	Do your HPLC software is 21CFR compliant?	All the stability study of EMPAGLIF (10mg & 25mg) Tablets has been conduct on Shimadzu HPLC (Model SPD-20) operated via **LABSOLUTION** software version 6.5 (complying FDA 21 CFR part 11),
31.	Can you show Audit Trail reports on New product testing?	Audit trail reports for Testing of Empaglif 10mg & 25mg Tablets are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm has some remaining quantities of stability batches kept in stability chamber for Real time stability.
33.	Do you have stability batches kept on stability testing?	Stability batches are kept in stability chamber for Real time stability testing. Up to 18 month Real time stability completed.
34.	Do you have valid calibration status for the equipments used for production and analysis of new product?	Firm has valid calibration status for equipment used in production and analysis of new products.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Proper and continuous monitoring record for stability chamber is available, along with 5KV backup generator with ATS.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities be rated as GMP compliant

Decision: Registration Board decided to approve registration of "Empaglif 10mg Tablet (Empagliflozin) & Empaglif 25mg Tablet (Empagliflozin) by M/s Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangle, Kahuta Road, Islamabad-25000, Pakistan. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Exemption cases

Sr. No.	Name and address of manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
8.	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi	GLARDIN-M Tablets 12.5mg + 500mg Each film coated tablet contains: Empagliflozin……12.5mg Metformin HCl USP…….500mg Anti-diabetic Manufacturer Specs.	Form 5D PKR 50,000/- 25-03-2016 14's : Rs. 4000/-	SYNJARDY Tablets 12.5mg + 500mg by Boehringer Ingelheim Pharmaceuticals, Inc., USA. (**USFDA** Approved) Last GMP Inspection dated 16-12-2019 concluding acceptable level of GMP compliance status
	Remarks of the Evaluator:			

STABILITY STUDY DATA			
Drug	GLARDIN-M Tablets 12.5mg + 500mg		
Name of Manufacturer	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi		
Manufacturer of API	Empagliflozin: M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China Metformin HCl: M/s Wanbury Limited India		
API Lot No.	Empagliflozin: 20171108 and 20190322 Metformin HCl: MT18751217		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time : 30◦C ± 2◦C / 75% ± 5%RH Accelerated: 40◦C ± 2◦C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,1,2,3,4,6 (months)		
Batch No.	488DS01	488DS02	488DS03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets

Manufacturing Date	22.05.2019	20.06.2019	20.06.2019
Date of Initiation	28-06-2019	10-07-2019	10-07-2019
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China (Certificate # JSHAHAQ2017005). The certificate is valid till 31-12-2020. Firm has submitted copy of GMP certificate of M/s Wanbury Limited India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice confirming import of 4 Kg Empagliflozin from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China dated 23-11-2017 for Batch No. 20171108 and 10 Kg Empagliflozin dated 05-04-2019 for Batch No. 20190322. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
Administrative Portion		
1	Reference of last onsite panel inspection for instant dosage form conducted during last two years	Firm has referred to onsite inspection report of their product for Arcox (Etoricoxib) Tablets 90mg & 120mg on 17th September, 2018 and was presented in 286th Drug Registration Board meeting held on 14th – 16th November, 2018. The case was approved and the inspection report confirms following points:

		• The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2	Documents for the procurement of API with approval from DRAP (in case of import)	Firm has submitted ADC attested invoice confirming import of 4 Kg Empagliflozin from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China dated 23-11-2017 for Batch No. 20171108 and 10 Kg Empagliflozin dated 05-04-2019 for Batch No. 20190322. Firm has submitted ADC attested invoice confirming import of 1000 Kg Metformin HCl from M/s Wanbury Limited India dated 16-01-2018 for Batch No. MT18751217.
3	Documents for the procurement of reference standard and impurity standards	Firm has submitted COA and invoice of reference standard and impurity standards.
4	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China (Certificate # JSHAHAQ2017005). The certificate is valid till 31-12-2020. Firm has submitted copy of GMP certificate of M/s Wanbury Limited India (Certificate # 3083/Stores/2019). The certificate is valid till 06-02-2022.
5	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation report of Empagliflozin and Metformin HCl, filled and signed by technical persons of the firm.
6	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, reference standard and impurity standards.
7	Documents for the procurement of excipients used in product development	Firm has submitted documents for procurement of excipients used in formulation of applied product.
8	List of qualified staff involved in product development with relevant experience	Firm has provided list of qualified staff of product development section and R&D Analytical Laboratory comprising of 43 qualified staff.
Production Data		
9	Authorized Protocols/SOP for the development & stability testing of trial batches	Firm has submitted authorized stability protocols / SOP for development and stability testing of trial batches.
10	Complete batch manufacturing record of three stability batches	Firm has submitted copy of Batch Manufacturing Record for all the three stability batches.
11	Record of remaining quantities of stability batches	Firm has provided following remaining quantities for each batch:

		488DS01 : 292 Tablets 488DS02 : 310 Tablets 488DS03 : 310 Tablets
QA/QC Data		
12	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing.
13	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of Empagliflozin and Metformin HCl.
14	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted copy of method of analysis of FPP and complete record of testing of stability batches along with chromatograms, lab reports, raw data sheets etc.
15	Reports of stability studies of API from manufacturer.	Firm has submitted stability studies reports of three batches of Empagliflozin and Metformin HCl.
16	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in product development
17	Drug-excipients compatibility studies.	Firm has submitted that same excipients has been used as used by innovator 'Synjardy Tablets 12.5mg + 500mg'. However, there is only difference in the film-coating material. Therefore, Drug-excipients compatibility studies were not performed.
18	Record of comparative dissolution data.	Firm has submitted data of comparative dissolution profile (in pH 1.2 HCl, Acetate Buffer pH 4.5, Phosphate buffer pH 6.8) with the innovator brand (Synjardy Tablets).
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.
Decision: Registration Board decided to approve registration of "GLARDIN-M Tablets 12.5mg + 500mg by M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi. Manufacturer will place first three commercial batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		

Agenda of Evaluator PEC-XIV

Case no. 01 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

9.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 24/26MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...24.3mg Valsartan as Sacubitril Valsartan sodium salt complex ……...25.7mg
	Diary No. Date of R& I & fee	2930, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5

	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 24/26mg by PharmEvo.
	GMP status	Inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.
	Remarks of Evaluator	
10.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 49/51MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...48.6mg Valsartan as Sacubitril Valsartan sodium salt complex ……...51.4mg
	Diary No. Date of R& I & fee	2931, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 49/51mg by PharmEvo.
	GMP status	Inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.
	Remarks of Evaluator	
11.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 97/103MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...97.2mg Valsartan as Sacubitril Valsartan sodium salt complex ……...102.8mg
	Diary No. Date of R& I & fee	2932, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 97/103mg by PharmEvo.
	GMP status	Inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.
	Remarks of Evaluator	

STABILITY STUDY DATA			
Name of Manufacturer	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar.		
Manufacturer of API	M/s Shandong Sihuan Pharmaceuticals Co., Ltd., Address: Nanyuan Road, Economic Development Zone, Pingyuan County, Dezhou City, Shandong Province, China.		
API Lot No.	2019021101		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40ºC ± 2ºC/75%±5% RH Real Time: 30ºC ± 2ºC/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,3,6 (06 months) Accelerated: 0,1,2,3,4,6 (06 months)		
Products applied	Batch No.	Batch Size	Manufacturing date
SACUVAL 24/26MG TABLET	T-49 T-50 T-51	1200 Tablets 1200 Tablets 1200 Tablets	06-06-2019 06-06-2019 06-06-2019
SACUVAL 49/51MG TABLET	T-52 T-53 T-54	1200 Tablets 1200 Tablets 1200 Tablets	06-06-2019 06-06-2019 06-06-2019
SACUVAL 97/103MG TABLET	T-55 T-56 T-57	1200 Tablets 1200 Tablets 1200 Tablets	06-06-2019 06-06-2019 06-06-2019
No. of Batches	03		
Date of Submission	26978 (13-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1. Sr. No.	Documents To Be Provided	Status
2.	COA of API.	Firm has submitted copy of COA of LCZ696 (Sacubitril/valsartan, batch # 2019021101) from M/s Shandong Sihuan Pharmaceutical Co., Ltd, China. Firm has submitted copy of COA of working standard from API supplier.
3.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued from Shandong Pharmaceutical Industry Association valid until 11-05-2021.
4.	Protocols followed for conduction of stability study and details of tests.	Yes
5.	Data of 03 batches will be supported by attested respective documents like	Yes

	chromatograms, laboratory reports, data sheets etc.	
6.	Documents confirming import of API etc.	The firm has submitted copy of invoice for the import of Raw material Sacubitril/Valsartan complex (1.5Kg) and copy of Form-6 attested by Assistant Director (I&E), DRAP, Peshawar dated 30-05-2019.
7.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
8.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
9.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

Sr. No.	Observations	Response of the firm
1.	Clarification is required since weight of raw material (Sacubitril/Valsartan) mentioned on courier slip is 0.5 Kg while that mentioned on commercial invoice is 1.5 Kg. Moreover, submitted commercial invoice is not attested by ADC DRAP.	The firm submitted that we purchased two different consignments from same source and mistakenly that list was attached. The firm has submitted copy of invoice for the import of Raw material Sacubitril / Valsartan complex (1.5Kg) and copy of Form-6 attested by Assistant Director (I&E), DRAP, Peshawar dated 30-05-2019.
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted	Firm has submitted copy of GMP certificate which is not issued by relevant regulatory authority.
3.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	We performed comparative dissolution which fall in limits for both our product and innovator.

Previous Decision: Registration Board deferred the case for following: (M-295)
Submission of GMP certificate of API manufacturer from concerned regulatory authority.
Submission of dissolution limits in finished product specifications in numerical values.

Evaluation by PEC: The firm has submitted GMP certificate for M/s Shandong Boyuan Pharmaceutical Co., Ltd. Qiangjin Street, Jibei Economic Development Zone, Jinan City, China issued by Shandong Food and Drug Administration, China valid till 25-08-2021. Previously submitted GMP certificate was for M/s Shandong Sihuan Pharmaceuticals Co., Ltd., Nanyuan Road, Economic Development Zone, Pingyuan County, Dezhou City, Shandong Province, China. The firm submitted agreement between M/s Shandong Boyuan Pharmaceutical Co., Ltd and M/s Shandong Sihuan Pharmaceuticals Co., Ltd and stated that all sacubitril-valsartan commercial goods will be manufactured in Shandong Boyuan Pharmaceutical Co., Ltd from 1st June 2019.

4. The firm submitted that we shall revise dissolution specifications as per innovator i.e., NLT (Q) in 25 min in commercial batch and accordingly, product test method will be updated.

INSPECTION REPORT VERIFICATION OF AUTHENTICITY OF STABILITY DATA

M/s Weather folds Pharmaceuticals Plot 69. Phase II Industrial Estate Hattar

Product:

1. Sacuval 24mg/26 mg Tablets
2. Sacuval 49mg/51 mg Tablets
3. Sacuval 97mg/103 mg Tablets

Date of inspection 01-09-2020 in compliance to letter No.F.1-/2020-PEC dated 01-09-2020

Q. No.	QUESTION	OBSERVATION BY PANEL
1.	Whether the firm has documents confirming import of API?	The firm has imported 1.5 Kg Sacubitril - Valsartan (LCZ696) API complex from M/s Shandong Sihuan Pharmaceutical Co., Ltd China. Form6, dated 30-05-2020
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm and the rationale behind selecting the manufacturer is its GMP status.
3.	Whether documents confirm the import of Valsartan/Sacubitril reference standard and impurity standards?	COA of working standard are available as supplied during shipment by the exporter.
4.	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from exporter?	COA of API and working standard LCZ696 available. Reference standard and impurities not imported.
5.	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP Certificate of API manufacturer issued by regulatory authority of country of origin (China).
6.	Whether firm use API manufacturer method of testing?	Firm has used manufacturer method for testing of co-crystallized API complex.
7.	Whether firm has stability studies reports on API?	Firm has accelerated and real time stability studies reports on API co-crystal complex Valsartan + Sacubitril performed by manufacturer of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed by manufacturer method, and manufacturer method is stability indicating (SIM). Degradation products have been quantified.
9.	Whether firm has method for quantifying the impurities in the API?	Firm has manufacturer validated method for quantifying impurities in API complex Valsartan + Sacubitril.
10.	Whether firm have some remaining quantities of the API, its reference standard and impurities standards?	Firm has consumed the co-crystal API Valsartan + Sacubitril.
11.	Whether firm has used pharmaceutical grade excipients?	All the excipients are pharmaceutical grade.

12.	Whether firm has documents confirming the import of the used excipients?	Local purchase for already registered products.
13.	Whether firm have test reports and other records on the excipients used?	Firm provided Lab test reports and certificate of analysis for all excipients.
14.	Whether firm has written and authorized protocols for the development of Valsartan + Sacubitril tablets?	Firm has written protocol for the development of Standard manufacturing procedure and batch processing sheet for manufacturing of trial batches.
15.	Whether firm has performed Drug-excipients compatibility studies?	The firm have not performed drug-excipients compatibility studies.
16.	Whether firm has performed comparative dissolution studies?	Firm has performed In vitro comparative dissolution studies with product (Savesto 50 mg (Getz Pharm), Uperio 100 mg and 200 mg)
17.	Whether firm has product development (R&D) section	No
18.	Whether firm has necessary equipment available in product development section for development of Valsartan + Sacubitril tablets?	No, firm have used existing manufacturing facility.
19.	Are the equipment in product development section qualified?	NA
20.	Whether firm have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	NA.
21.	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff with proper knowledge with respect to product development.
22.	Whether firm has manufactured three stability batches for the stability studies of Valsartan + Sacubitril Tablets as required?	Firm has manufactured three stability batches for each.
23.	What were the criteria for fixing the batch size of stability batches?	Criteria for fixing batch size of stability batches is number of tablets per testing and number of testing frequencies according to 276th DRB meeting.
24.	Whether firm has complete record of production of stability batches?	Firm has complete record of production of stability batches.
25.	Whether firm have protocols for stability testing of stability batches?	Real time stability studies: 0, 3rd, 6th, 9th, 12th, 18th and 24th months Accelerated stability studies: 0, 1st, 2nd, 3rd, 4th & 6th months as per 276 DRB meeting.
26.	Whether firm has developed and validated the method for testing of stability batches?	Firm has used In-house validated HPLC method for testing of Assay and Dissolution in stability batches.
27.	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	In house methods.

28.	Whether firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Valsartan + Sacubitril API and the finished drug?	Yes
29.	Whether firm has stability indicating method of analysis?	Method stability indicating.
30.	Whether firm has HPLC software 21CFR compliant?	Yes, Empower2,waters , 600 series
31.	Whether firm could you show Audit Trail reports on Valsartan + Sacubitril testing?	Audit trail on the testing reports were provided by the firm and demonstrated accordingly.
32.	Whether firm have some remaining quantities of degradation products and stability batches?	Stability batches available.
33.	Whether firm has commitment batches kept on stability testing?	Firm has three commitment batches kept on stability testing in stability chamber at real time stability conditions.
34.	Whether firm has valid calibration status for the equipment used in Valsartan + Sacubitril tablets production and analysis?	Firm has proper calibration schedule and valid calibration status for the equipment used in Valsartan + Sacubitril tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	21CFR compliant, The chambers have been provided with continuous power supply (power backup up to 12hrs) and digital data loggers with record of test period.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm was operating under satisfactory level of cGMP compliance.

Conclusions:

a. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Sacuval 24mg/26 mg Tablets (Sacubitril as Sacubitril valsartan sodium salt complex 24.3mg, valsartan as Sacubitril Valsartan sodium salt complex25.7mg), Sacuval 49mg/51 mg Tablets (Sacubitril as Sacubitril valsartan sodium salt complex 48.6mg, valsartan as Sacubitril Valsartan sodium salt complex 51.4mg), Sacuval 97mg/103 mg Tablets (Sacubitril as Sacubitril valsartan sodium salt complex 97.2mg, valsartan as Sacubitril Valsartan sodium salt complex 102.8mg) is verifiable to satisfactory level and the panel recommends grant of registration for the above mentioned products.

Decision: Registration Board decided to approve registration of "SACUVAL 24/26MG TABLET, SACUVAL 49/51MG TABLET, SACUVAL 97/103MG TABLET by M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar. Manufacturer will place first three commercial batches of all three products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Case No.2 Registration applications of local manufacturing of human drugs submitted on CTD format (New Section)

On the recommendations of panel of experts, the CLB in its 271st meeting held on 12th September has considered and approved the following two additional sections to firm M/s News Pharma, plot No. 42, Sundar Industrial Estate, Lahore

- Dry Powder Suspension (Cephalosporin) Section (1 molecule / 2 Products)
- Capsule (cephalosporin) Section

12.	Name, address of Applicant / Marketing Authorization Holder	M/s News pharma, Plot No. 42, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s News pharma, Plot No. 42, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of panel inspection dated 24-07-2019 wherein firm was granted two additional section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27th September, 2019 specifying Dry Powder Suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22467 : 03-09-2020
	Details of fee submitted	PKR 20,000/-: 11-08-2020,
	The proposed proprietary name / brand name	New-Xime DS 200mg / 5ml Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml (after reconstitution) contains: Cefixime as trihydrate……..200mg
	Pharmaceutical form of applied drug	Dry Powder for Oral Suspension
	Pharmacotherapeutic Group of (API)	Third Generation Cephalosporin (J01DD08)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 x30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax 200mg / 5ml Powder for oral suspension (USPFDA approved)
	For generic drugs (me-too status)	Caricef DS 200mg / 5ml of M/s Sami pharma (Reg # 044340)
	Name and address of API manufacturer.	M/s PHARMAGEN LIMITED, Kot Nabi Bukshwala, 34 Km, Ferozpur Road , Lahore (Cefixime Micronised)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 36 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted pharmaceutical equivalence with comparator product Caricef DS 200mg/5ml Dry suspension.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method and referred to USP monograph in module III.
13.	Name, address of Applicant / Marketing Authorization Holder	M/s News pharma, Plot No. 42, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s News pharma, Plot No. 42, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm has submitted copy of panel inspection dated 24-07-2019 wherein firm was granted two additional section.

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27th September, 2019 specifying Dry Powder Suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22466 : 03-09-2020
	Details of fee submitted	PKR 20,000/-: 11-08-2020,
	The proposed proprietary name / brand name	New-Xime 100mg / 5ml Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml (after reconstitution) contains: Cefixime as trihydrate……..100mg
	Pharmaceutical form of applied drug	Dry Powder for Oral Suspension
	Pharmacotherapeutic Group of (API)	Third Generation Cephalosporin (J01DD08)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 x30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax 100mg / 5ml Powder for oral suspension (USPFDA approved)
	For generic drugs (me-too status)	Caricef DS 100mg / 5ml of M/s Sami pharma (Reg # 022415)
	Name and address of API manufacturer.	M/s PHARMAGEN LIMITED, Kot Nabi Bukshwala, 34 Km, Ferozpur Road , Lahore (Cefixime Micronised)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 36 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted pharmaceutical equivalence with Caricef DS 200mg/5ml Dry suspension in one medium.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of validation studies of analytical method and referred to USP monograph in module III.

STABILITY STUDY DATA

Manufacturer of API	M/s PHARMAGEN LIMITED, Kot Nabi Bukshwala, 34 Km, Ferozpur Road , Lahore (Cefixime Micronised)		
API Lot No.	00243 / 166 / 2019		
Description of Pack (Container closure system)	Amber Glass Bottle, 1's		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Products applied	Batch No.	Batch size	Manufacturing date
New-Xime DS 200mg/5ml Dry Suspension	T-01 T-02 T-03	150 bottles 150 bottles 150 bottles	10-2019 10-2019 10-2019
New-Xime 100mg/5ml Dry Suspension	T-01 T-02 T-03	150 bottles 150 bottles 150 bottles	10-2019 10-2019 10-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Pharmagen Ltd, Lahore issued by DRAP Lahore. It is valid till 07-01-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying local purchase of 1.0Kg of Cefixime (micronized) dated 15-10-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted that it is not applicable as stability study started in November 2019and it was decided in 293rd meeting which was held in January 2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

REMARKS OF EVALUATOR

<table>
<tr><th>Sr. No.</th><th>Observations communicated</th><th>Response by the firm</th></tr>
<tr><td>25.</td><td>Submit data in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board which states that “Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product.”</td><td>The firm has submitted that study was performed after reconstitution with boiled, cooled water and no significant change in odor, taste or assay was observed.</td></tr>
<tr><td>26.</td><td>Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided.</td><td>Following studies were performed on New-Xime powder for suspension after reconstitution with boiled, cooled water:
<table>
<tr><th>Day</th><th>Change in odor</th><th>Change in Taste</th><th>Assay</th></tr>
<tr><td>01</td><td>No</td><td>No</td><td>99.97%</td></tr>
<tr><td>03</td><td>No</td><td>No</td><td>99.96%</td></tr>
<tr><td>05</td><td>No</td><td>No</td><td>99.43%</td></tr>
<tr><td>07</td><td>No</td><td>No</td><td>98.90%</td></tr>
</table></td></tr>
<tr><td>27.</td><td>Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.</td><td>The firm has submitted batch manufacturing records of all the batches of drug product.</td></tr>
<tr><td>28.</td><td>Submit description of the primary container closure systems, including materials of construction as per section 3.2.P.7.</td><td>The firm has used Amber Glass bottle of USP Type III.</td></tr>
<tr><td>29.</td><td>Pharmacological group has been mentioned as 1st generation cephalosporin antibiotic. Clarification is required.</td><td>The firm has corrected the pharmacological group as 3rd Generation cephaloporins.</td></tr>
<tr><td>30.</td><td>Provide summarized tabulated results of verification studies including</td><td>The firm has submitted summary of verification studies of drug product.</td></tr>
</table>

	specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance under section 2.3.S.4.3.	
31.	Data of stability batches is not supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets. Submission of documents is required.	The firm has submitted supporting documents like chromatograms, raw data sheets, COAs and summary data sheets.

Decision: Registration Board decided to approve registration of New-Xime 100mg / 5ml Dry Suspension and New-Xime DS 200mg / 5ml Dry Suspension:

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda of AD PEC-III

Case No. 01

1. **REPORT OF VERIFICATION OF AUTHENTICITY OF PRODUCT DEVELOPMENT / STABILITY DATA AND CAPACITY ASSESSMENT FOR CONTRACT MANUFACTURING**

General Information

Name of manufacturer	M/s. Seraph pharmaceuticals (Pvt.) ltd.
Physical Address	Plot # 210, Industrial Triangle, Kahuta Road, Islamabad
Manufacturing Enlistment No.	000860
Date of inspection	03-09-2020
Purpose of inspection	Verification of Authenticity of Product Development/Stability Data And Capacity Assessment with reference to DRAP, Islamabad letter No. F.1-2/2020-PEC dated 27-08-2020.
Dosage Form/Sections Included	i. Dry Powder Injection (Cephalosporin) Section ii. Dry Powder for Suspension (Cephalosporin) Section iii. Capsule (Cephalosporin) Section
Name of inspector (s)	i. Dr. Qurban Ali, Member Registration Board ii. Mr. Haseeb Tariq, Assistant Director, PEC, PE&R Division iii. Mr. M. Ahsan Hafiz, Assistant Director, PEC, PE&R Division
Name of Firm's Representative (s) accompanying during inspection	i. Qazi Abdur Rasheed (Production Incharge) ii. Faisal Siddiqui (Quality Control Manager) iii. Inam ul Haq (QA Incharge)

Manufacturing record/data was evaluated from **July 2019 to June 2020** for the said purpose. The details of capacity calculations are as under:

SECTION WISE CAPACITY CALCULATION

Capacity of Cephalosporin Injectable Section

Step wise capacity of Cephalosporin Injectable manufacturing	Capacity
Vial Washing - Per single shift of 8 working hours (Load per Day)	32,000 vials
Vial Washing - Per month (22 working Days) with single shift of 8 working hours	704,000 vials
Depyrogenation Capacity- Per Single shift of 8 working hours (Load per Day)	28,000 vials
Depyrogenation Capacity- Per month (22 working Days) with single shift of 8 working hours	6,16,000 vials
Filling and Sealing Capacity – Per single shift of 8 working hours(Load per Day)	56,000 vials
Filling and Sealing Capacity – Per month (22 working Days) with single shift of 8 working hours	12,32,000 vials
Packing Capacity – Per single shift of 8 working hours	21,600 Packs (Vials)
Packing Capacity– Per month (22 working Days) with single shift of 8 working hours	475,200 Packs (Vials)

Note: Limiting step in this process is Packing for calculating Utilized Capacity.

Quarter Wise capacity utilized in Tablet Section			
Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in (%)**
3rd- 2019	300985	1425600	21.12
4th-2019	377816	1425600	26.53
1st-2020	263461	1425600	18.49
2nd -2020	218662	1425600	15.34
Average Capacity Utilized for 2019-2020 in %			**20.37**

Manufacturing Capacity Utilized (average): 20.37%
Manufacturing Capacity Available (average): 79.63%

Capacity of Cephalosporin Dry Powder Suspension

Step wise Capacity of Cephalosporin Dry Powder Suspension	Capacity
Air Blowing Capacity - Per single shift of 8 working hours (Load per Day)	20,000 Bottles
Air Blowing Capacity Per month (22 working Days) with single shift of 8 working hours	440,000 Bottles
Mixing Capacity - Per single shift of 8 working hours (Load per Day)	300 Kg
Mixing Capacity Per month (22 working Days) with single shift of 8 working hours	6,600 Kg
Filling Capacity – Per single shift of 8 working hours (Load per Day)	12,000 Bottles

Filling Capacity – Per month (22 working Days) with single shift of 8 working hours	264,000 Bottles
Packing Capacity – Per single shift of 8 working hours	12,000 Packs
Packing Capacity – Per month (22 working Days) with single shift of 8 working hours	264,000 Packs

Note: Limiting step in this process is filling and packing process for calculating Utilized Capacity.

Quarter wise Capacity utilized			
Quarter	**Actual Production (Bottles)**	**Capacity (Bottles)**	**Capacity utilized in (%)**
3rd- 2019	57394	792000	7.25
4th-2019	89455	792000	11.29
1st-2020	24473	792000	3.09
2nd -2020	59429	792000	7.50
Average Capacity Utilized for 2019-2020 in %			7.28

Manufacturing Capacity Utilized (average): 7.28%
Manufacturing Capacity Available (average): 92.72%

Capacity of Cephalosporin Capsule Section

Step wise capacity of Capacity of Hard Gelatin Capsule Section	**Capacity**
Mixing Capacity - Per single shift of 8 working hours (Load per Day)	300 Kg
Mixing Capacity Per month (22 working Days) with single shift of 8 working hours	6,600 Kg
Filling Capacity – Per single shift of 8 working hours (Load per Day)	100,000 Capsules
Filling Capacity – Per month (22 working Days) with single shift of 8 working hours	22,00,000 Capsules
Blistering Capacity – Per single shift of 8 working hours	32000 Blisters
Blistering Capacity – Per month (22 working Days) with single shift of 8 working hours	704000 Blisters
Packing Capacity – Per single shift of 8 working hours	21,600 Packs
Packing Capacity – Per month (22 working Days) with single shift of 8 working hours	475,200 Packs

Note: Limiting step in this process is Packing Process for calculating Utilized Capacity.

Quarter Wise Capacity of Cephalosporin Hard Gelatin Capsule Section			
Quarter	**Actual Production (Capsules)**	**Capacity (Capsules)**	**Capacity utilized in (%)**
3rd- 2019	2,70,515	1425600	18.98 %
4th-2019	4,21,953	1425600	29.60 %
1st-2020	1,12,373	1425600	7.88 %
2nd -2020	1,85,070	1425600	12.98 %

Average Capacity Utilized for 2019-2020 in %	17.36 %

Manufacturing Capacity Utilized (average): 17.36%
Manufacturing Capacity Available (average): 82.64%

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details			
Sr. No.	Equipments	Qty.	Capacity per day (tests)
1	HPLC	2	2x2 = 4
2	UV Spectrophotometer	1	20
3	pH Meter	2	50
4	Polarimeter	1	15
5	Dissolution apparatus	2	16
6	Balance	1	50
7	Moisture Analyzer	1	20
8	Melting Point Apparatus	1	20
10	Viscometer	1	20
11	Cold Incubator	1	500L
12	Hot incubator	4	125L x 4 = 500L
13	Filtration assembly	2	6

HPLC Capacity Calculation Quarter Wise
(Average 2 tests/day/HPLC)
TOTAL 2 HPLC

QUARTER	Average Capacity of 2 HPLCs	Performed	Capacity Utilized %	Capacity Available %
III/2019	138	51	28.98	71.02
IV/2019	138	47	28.98	71.02
I/2020	138	37	22.46	77.54
II/2020	138	31	14.49	85.51
Average capacity Available:			**23.73**	**76.27**

UV Spectrophotometer Capacity Calculation Quarter Wise (Average 20 tests/day)				
Description	Capacity	Performed	Capacity Utilized %	Capacity Available %
III/2019	1380	32	2.31%	97.69%
IV/2019	1380	34	2.46%	97.54%
I/2020	1380	133	9.63%	90.37%
II/2020	1380	65	4.71%	95.29%
Average capacity Available:				**95.22%**

Capacity Calculation for sterility testing Quarter Wise (Average 6 tests/day)				
Description	Capacity	Tests Performed	Capacity Utilized %	Capacity Available %
III/2019	396	40	10.10	87.68%
IV/2019	396	40	10.10	91.06%
I/2020	396	31	7.83	88.65%
II/2020	396	20	5.05	92.51%
Average capacity available:				**89.98%**

Capacity Calculation for Bacterial Endotoxin Test Quarter Wise (Average 10 tests/day)				
Description	Capacity	Tests Performed	Capacity Utilized %	Capacity Available %
III/2019	660	50	13.20	86.80
IV/2019	660	50	13.20	86.80
I/2020	660	39	5.90	94.1
II/2020	660	25	3.79	96.21
Average capacity available:				**90.98%**

1. Total number of registered products and registered products in aforementioned sections:

Total registered products of the firm: 172

Registered products in the aforementioned sections: 28

Existing registered products on contract manufactured by the firm in aforementioned sections: 27

2. Manufacturing, QC and IPQC testes performed on manufactured products:

The details of QC and IPQC tests performed on the products manufactured in aforementioned sections are as given in **ANNEX 1**.

3. Installed and utilized capacity of these sections:

The installed and utilized capacity of production in these sections, as provided by the firm, has been given in detail earlier in the report.

4. Installed and utilized capacity of QC Equipment as per pharmacopoeial reference:

The installed and utilized capacity of QC equipment used for testing of products related to these sections, as provided by the firm, has been given in detail earlier in the report.

List of technical personnel **(ANNEX 2)** and list of machinery/equipment **(ANNEX 3)** is attached with the report.

CONCLUSION

The manufacturing capacity (installed, utilized and unutilized) of M/s. Seraph pharmaceuticals (Pvt.) Ltd., Plot # 210, Industrial Triangle, Kahuta Road, Islamabad was assessed based on the data and record provided by the firm, interview of the personnel and visit of the premises.

The details along with the additional points have been given in the report for record and further necessary action.

Decision: Registration Board referred the case back to the panel to assess overall capacity of the analytical equipment of firm including HPLC keeping in view pharmacopoeial and other requirements of all registered drug products.

Case no. 02 Registration applications of CTD cases

A. New Cases

New DML:

M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad was granted new license by way of formulation dated 06-11-2019. The firm has submitted following applications on CTD format.

No. of molecules: 01 / No. of Products: 02		
14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25473: 29-11-2019 (Form 5) Dy. No. 22258: 02-09-2020 (Form 5F)
	Details of fee submitted	PKR 20,000/-: 28-11-2019
	The proposed proprietary name / brand name	**MENEPOR 500 mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem……..500mg
	Pharmaceutical form of applied drug	Glass vial filled with almost white powder along with 10ml ampoule of WFI further packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Firm has not submitted verification studies of analytical method for the testing of drug substance.**
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. **Firm has used overage in the formulation of trial batches**
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Meronem 500mg injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
API Lot No.	UIMRPS19021
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MR-001	MR-002	MR-003
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/214) issued by Drugs control organization dated 23-01-2020. The certificate is valid till 26-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg meropenem.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and report for verification studies of the analytical procedure for drug substance.
Provide scientific justification for the use of overage in development of the trial batches.	Firm has submitted that they have not used any overage but did the potency adjustment as per the raw material analysis
Submit the data of compatibility studies in section 3.2.P.2.6 to comply the decision of 293rd meeting of Registration Board, which states that "Compatibility studies for the dry powder for	Firm has submitted the results of appearance, pH and assay after reconstitution with water for injection.

injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	
Submit data in section 3.2.P.5.3 as per the decision of 293rd meeting of Registration Board, which states that "All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification should include a demonstration of specificity, repeatability (method precision) and accuracy. You have submitted verification report which states that testing is conducted at chemical laboratory of Bio-Labs, further the parameters like specificity, repeatability (method precision) are not determined.	Firm has submitted protocols and report for verification studies of drug product which includes test of specificity, accuracy and repeatability. The report specifies that the verification studies was carried out in chemical lab of Bio-Next Pharmaceuticals.
Submit data in section 3.2.P.6 as per the decision of 293rd meeting of Registration Board, which states that "COA of primary / secondary reference standard including source and lot number shall be provided." You have submitted certificate of analysis of the API instead of reference standard.	Firm has submitted COA of primary reference standard from USP. Reference standard from API manufacturer is **not** submitted.
Specify the type of glass vial used for the applied product.	Firm has submitted that they will use type **II** glass vial.
Provide the data of in-use stability studies in section 3.2.P.8 as per the decision of 293rd meeting of Registration Board, which states that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided."	Firm has submitted that after reconstitution the product is to be used immediately therefore in-use stability data is not applicable.
Complete audit trail report for all the HPLC tests of the applied product needs to be submitted.	Firm has submitted that they have performed stability studies on Agilent HPLC which is 21 CFR compliant working via openLab CDS (Revision No. 2.3) compliance software.

Decision: Registration Board decided to approve registration of MENEPOR 500mg Injection IV

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25474: 29-11-2019 (Form 5) Dy. No. 22257: 02-09-2020 (Form 5F)
	Details of fee submitted	PKR 20,000/-: 28-11-2019
	The proposed proprietary name / brand name	**MENEPOR 1g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem……..1g
	Pharmaceutical form of applied drug	Glass vial filled with almost white powder along with 20ml ampoule of WFI further packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Firm has not submitted verification studies of**

		analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. **Firm has used overage in the formulation of trial batches**
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Meronem 500mg injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.	UIMRPS19021		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MR-004	MR-005	MR-006
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/214) issued by Drugs control organization dated 23-01-2020. The certificate is valid till 26-02-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg meropenem.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and report for verification studies of the analytical procedure for drug substance.
Provide scientific justification for the use of overage in development of the trial batches.	Firm has submitted that they have not used any overage but did the potency adjustment as per the raw material analysis
Submit the data of compatibility studies in section 3.2.P.2.6 to comply the decision of 293rd meeting of Registration Board, which states that "Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product"	Firm has submitted the results of appearance, pH and assay after reconstitution with water for injection.
Submit data in section 3.2.P.5.3 as per the decision of 293rd meeting of Registration Board, which states that "All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification should include a demonstration of specificity, repeatability (method precision) and accuracy. You have submitted verification report which states that testing is conducted at chemical laboratory of Bio-Labs, further the parameters like specificity,	Firm has submitted protocols and report for verification studies of drug product which includes test of specificity, accuracy and repeatability. The report specifies that the verification studies was carried out in chemical lab of Bio-Next Pharmaceuticals.

repeatability (method precision) are not determined.	
Submit data in section 3.2.P.6 as per the decision of 293rd meeting of Registration Board, which states that "COA of primary / secondary reference standard including source and lot number shall be provided." You have submitted certificate of analysis of the API instead of reference standard.	Firm has submitted COA of primary reference standard from USP. Reference standard from API manufacturer is **not** submitted.
Specify the type of glass vial used for the applied product.	Firm has submitted that they will use type **II** glass vial.
Provide the data of in-use stability studies in section 3.2.P.8 as per the decision of 293rd meeting of Registration Board, which states that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf life should be provided."	Firm has submitted that after reconstitution the product is to be used immediately therefore in-use stability data is not applicable.
Complete audit trail report for all the HPLC tests of the applied product needs to be submitted.	Firm has submitted that they have performed stability studies on Agilent HPLC which is 21 CFR compliant working via openLab CDS (Revision No. 2.3) compliance software.

Decision: Registration Board decided to approve registration of MENEPOR 1gmInjection IV

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Evaluator PEC-I

Case No. I: Capacity Assessment of M/s Safe Pharmaceuticals, Karachi

CAPACITY ASSESSMENT INSPECTION OF MS. SAFE PHARMACEITICALS PRIVATE LIMITED

Physical Address:	Plot No. CI-20 & 21 Sector-6/B North Karachi industrial area Karachi.
Date of inspection:	13th March 2020
Purpose of inspection:	To determine the manufacturing surplus capacity.
DRAP Islamabad reference letter No. & Date:	F.1-2/2020/PEC, 24th February 2020
Names of inspectors	Dr. Najam-Us-Saquib Additional Director DRAP Karachi. Abdul Rasool Shaikh Area FID Karachi
Names of firm's representatives:	Muhammad Farooq Memon, CE of the firm.

BRIEF ABOUT FIRM:

M/s. Safe Pharmaceuticals (Pvt) Ltd: situated at Plot No. CI-20 & 21 Sector-6/B North Karachi industrial area Karachi was visited and inspected in the light of the above letter to gauge their manufacturing surplus capacity. The firm is famous for manufacturing certain generic products and as per approved design the firm has facilities to manufacture Tablet (G), Tablet (Psychotropic), Capsule (G), Capsule (Cephalosporin), Liquid Syrup, Sterile Liquid Injection General (ampoule/vial), Dry Powder Suspension (G), Dry Powder Suspension (Cephalosporin), Sterile Lyophilized Dry Powder injection (G), Sterile Dry Powder Injection (Cephalosporin).

The firm bears DML No. 000349 by way of formulation and that is valid till 02/2025. In all the approved sections the firm has 309 numbers of registrations excluding registrations for export and for contract manufacturing, which is around 91. Among all the registrations around 210 are regularly manufactured as per records reviewed during the visit. The firm was seen well-maintained at the time of inspection with respect to sanitation & hygiene, documentation and good practices in production, QC lab and stores. The firm was further inspected as per TORs and relevant manufacturing, packaging and quality control records for previous year were reviewed in detail and concluded as follows:

Manufacturing record/data was evaluated from July, 2019 to June, 2020 for the said purpose. The details of capacity calculations are as under:-

SECTION WISE CAPACITY CALCULATION

CAPACITY OF DRY POWDER INJECTION (CEPHALOSPORIN)

Step wise capacity of Cephalosporin Injectable manufacturing	Capacity
Vials Washing: Per single shift of 8 working hours (Load per Day)	50,000 Vials
Vials Washing: Per month (25 working Days) with single shift of 8 working hours	1,250,000 Vials
Depyrogenation Capacity: Per single shift of 8 working hours (Load per Day)	37,000 Vials
Depyrogenation Capacity: Per month (25 working Days) with single shift of 8 hours	925,000 Vials
Filling and Sealing Capacity: Per single shift of 8 working hours (Load per Day)	50,000 Vials
Filling and Sealing Capacity: Per month (25 working Days) with single shift of 8 hours	1,250,000 Vials
Labeling Capacity: Per single shift of 8 working hours (Load per Day)	50,000 Vials
Labeling Capacity: Per month (25 working Days) with single shift of 8 hours	1,250,000 Vials
Packing Capacity: Per single shift of 8 working hours	50,000 Vials
Packing Capacity: Per month (25 working Days) with single shift of 8 hours	1,250,000 Vials

Note: Limiting step in this process is Depyrogenation process for calculation Utilized Capacity

Quarter Wise capacity utilized in Cephalosporin Injectable Section			
Quarter	Actual Production (Vials)	Capacity (Vials)	Capacity utilized in %
3rd - 2019	903,031	2,775,000	32.54%
4th - 2019	478,236	2,775,000	17.23%
1st - 2020	774,297	2,775,000	27.90%

2nd - 2020	701,534	2,775,000	25.28%
Total	2,857,098	11,100,000	--
Average per Quarter	714,275	2,775,000	25.74%

Manufacturing Capacity Utilized (Average) = 25.74%
Manufacturing Capacity Available (Average) = 74.26%

CAPACITY OF DRY POWDER INJECTION GENERAL/LYOPHILIZED) SECTION

Step wise capacity of Cephalosporin Injectable manufacturing	Capacity
Vials Washing: Per single shift of 8 working hours (Load per Day)	30,000 Vials
Vials Washing: Per month (25 working Days) with single shift of 8 working hours	750,000 Vials
Depyrogenation Capacity: Per single shift of 8 working hours (Load per Day)	18,500 Vials
Depyrogenation Capacity: Per month (25 working Days) with single shift of 8 hours	462,500 Vials
Filling and Sealing Capacity: Per single shift of 8 working hours (Load per Day)	15,000 Vials
Filling and Sealing Capacity: Per month (25 working Days) with single shift of 8 hours	375,000 Vials
Labeling Capacity: Per single shift of 8 working hours (Load per Day)	15,000 Vials
Labeling Capacity: Per month (25 working Days) with single shift of 8 hours	375,000 Vials
Packing Capacity: Per single shift of 8 working hours	50,000 Vials
Packing Capacity: Per month (25 working Days) with single shift of 8 hours	1,250,000 Vials

Note: Limiting step in this process is Filling & Sealing process for calculation Utilized Capacity

Quarter Wise capacity utilized in Dry Powder General Section			
Quarter	Actual Production (Vials)	Capacity (Vials)	Capacity utilized in %
3rd - 2019	60,907	375,000	16.24%
4th - 2019	171,929	375,000	45.85%
1st - 2020	100,486	375,000	26.80%

2nd - 2020	162,015	375,000	43.20%
Total	495,337	1,500,000	--
Average per Quarter	123,834	375,000	33.02%

Manufacturing Capacity Utilized (Average)= 33.02%
Manufacturing Capacity Available Average) = 66.98%

CAPACITY OF LIQUID INJECTABLE SECTION (AMPOULES)

Step wise capacity of Liquid Injectable (Ampoule) Section	Capacity
Ampoule Washing: Per single shift of 8 working hours (Load per Day)	240,000 Ampoule
Ampoule Washing: Per month (25 working Days) with single shift of 8 working hours	6,000,000 Ampoule
Ampoule Depyrogenation: Per single shift of 8 working hours (Load per Day)	100,000 Ampoule
Ampoule Depyrogenation: Per month (25 working Days) with single shift of 8 hours	2,500,000 Ampoule
Mixing: Per single shift of 8 working hours (Load per Day)	1,000 Litres
Mixing: Per month (25 working Days) with single shift of 8 hours	25,000 Litres
Ampoule Filling: Per single shift of 8 working hours	140,000 Ampoules (5ml)
Ampoule Filling: Per month (25 working Days) with single shift of 8 hours	3,500,000 Ampoules (5ml)
Terminal Sterilization: Per single shift of 8 working hours	120,000 Ampoules
Terminal Sterilization: Per month (25 working Days) with single shift of 8 hours	3,000,000 Ampoules
Packing Capacity: Per single shift of 8 working hours	5's 40,000 Packs 10's 20,000 Packs 25's 8,000 Packs
Packing Capacity: Per month (25 working Days) with single shift of 8 hours	5's 1,000,000 Packs 10's 500,000 Packs 25's 200,000 Packs

Note: Limiting step in this process is Depyrogenation process and Terminal Sterilization and all batch sizes are designed according to these limitations.

Quarter Wise capacity of Liquid Injectable (Ampoule) Section			
Quarter	Actual Production (Ampoules)	Capacity (Ampoules)	Capacity utilized in %

3rd -2019	2,168,015	7,500,000	28.91%
4th -2019	3,135,400	7,500,000	41.81%
1st-2020	2,301,998	7,500,000	30.69%
2nd -2020	2,907,467	7,500,000	38.77%
Total	10,512,880	30,000,000	--
Average per Quarter	2,628,220	7,500,000	35.04%

Manufacturing Capacity Utilized (Average) = 35.04%
Manufacturing Capacity Available (Average) = 64.96%

CAPACITY OF LIQUID INJECTABLE SECTION (VIALS)

Step wise capacity of Liquid Injectable (Vials) Section	Capacity
Vials Washing: Per single shift of 8 working hours (Load per Day)	10,000 Vials
Vials Washing: Per month (25 working Days) with single shift of 8 working hours	250,000 Vials
Vials Depyrogenation: Per single shift of 8 working hours (Load per Day)	10,000 Vials
Vials Depyrogenation: Per month (25 working Days) with single shift of 8 hours	250,000 Vials
Mixing: Per single shift of 8 working hours (Load per Day)	1,000 Litres
Mixing: Per month (25 working Days) with single shift of 8 hours	250,000 Litres
Vials Filling: Per single shift of 8 working hours	10,000 Vials (100ml)
Vials Filling: Per month (25 working Days) with single shift of 8 hours	250,000 Vials (100ml)
Terminal Sterilization: Per single shift of 8 working hours	10,000 Vials
Terminal Sterilization: Per month (25 working Days) with single shift of 8 hours	250,000 Vials
Labeling Capacity: Per single shift of 8 working hours (Load per Day)	10,000 Vials
Labeling Capacity: Per month (25 working Days) with single shift of 8 hours	250,000 Vials
Packing Capacity: Per single shift of 8 working hours	10,000 Packs (Vials)
Packing Capacity: Per month (25 working Days) with single shift of 8 hours	250,000 Packs (Vials)

Note: Limiting step in this process is Depyrogenation process and Terminal Sterilization process for calculating utilized capacity

Quarter Wise capacity of Liquid Injectable (Vials) Section			
Quarter	Actual Production (Vials)	Capacity (Vials)	Capacity utilized in %
3rd -2019	90,965	750,000	12.13%
4th -2019	127,219	750,000	16.96%
1st-2020	109,408	750,000	14.59%
2nd -2020	130,077	750,000	17.34%
Total	457,669	3,000,000	--
Average per Quarter	114,417	750,000	15.26%

Manufacturing Capacity Utilized (Average) = 15.26%
Manufacturing Capacity Available (Average) = 84.74%

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details							
S. #	Equipment	Qty.	Capacity per day (tests)	Capacity per month (tests)	Average utilization/month (tests)	Capacity utilization (%age)	Capacity available %age)
1	HPLC	3	3 x 2 = 6	150	75	50%	50%
2	UV Spectrophotometer	2	2 x 15 = 30	750	300	40%	60%
3	FTIR	1	50	1250	450	36%	64%
4	pH Meter	1	50	1250	750	60%	40%
5	Balance	2	-	-	-	-	-
6	Moisture Analyzer	1	50	1250	500	40%	60%
7	Melting Point Apparatus	1	20	500	125	25%	75%
8	Liquid Particle Counter	1	40	1000	200	20%	80%
9	Cold Incubator	2	1 x 164 L 1 x 53 L	-	-	-	-
10	Hot Incubator	1	1 x 53 L	-	-	-	-
11	Karl Fisher	1	25	625	375	60%	40%
12	Air Particle Counter	2	-	-	-	-	

Total number of registered products and registered products in aforementioned sections:

Total registered products:	309
Registered products in aforementioned sections	97
Existing contract manufactured products in aforementioned sections	45
Registered products (Export) in aforementioned sections	17

CAPACITY OF DRY POWDER INJECTION (CEPHALOSPORIN)

SAFE Pharma Registration	SAFE Pharma Export Registration	SAFE Pharma Pending Applications	Contract Products Registrations	Contract products Pending Applications
31	10	4	23	14

CAPACITY OF DRY POWDER INJECTION (GENERAL/LYOPHILIZED) SECTION

SAFE Pharma Registration	SAFE Pharma Export Registration	SAFE Pharma Pending Applications	Contract Products Registrations	Contract products Pending Applications
12	0	5	7	26

CAPACITY OF LIQUID INJECTABLE SECTION (AMPOULES)

SAFE Pharma Registration	SAFE Pharma Export Registration	SAFE Pharma Pending Applications	Contract Products Registrations	Contract products Pending Applications
42	7	15	11	28

CAPACITY OF LIQUID INJECTABLE SECTION (VIALS)

SAFE Pharma Registration	SAFE Pharma Export Registration	SAFE Pharma Pending Applications	Contract Products Registrations	Contract products Pending Applications
12	0	4	3	11

Conclusion:

The above calculations were made on installed capacity of each section, actual quantity manufactured and finished quantity stocked or sold into the market for the period from July 2019 to June 2020. The panel further examined with respect to time consumption, each process starting form cleaning of ampoules /vials, washing, drying, filling, sealing, packing, testing and storage of above dosage forms.

Based on a thorough inspection the panel unanimously concluded an ample surplus capacity in the stated sections which could better be utilized in contract manufacturing for other registered manufacturers.

Decision: Registration Board referred the case back to the panel to assess overall capacity of the analytical equipment of firm including HPLC keeping in view pharmacopoeial and other requirements of all registered drug products.

Case No.01: ALLOCATION OF QUOTA FOR CONTROL SUBSTANCES EPHEDRINE HCL FOR THE YEAR 2017 TO M/S. SHAREX LABORATORIES, SADIQABAD.

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below:-

Proceedings of 275th of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product ―Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the comittee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product ―Tracodil Syrup‖ (Reg no. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

Decision of 275th meeting of Registration Board:-

Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

Proceedings of 286th meeting of Registration Board:-

Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product ―Tracodil syrup (Reg.003158) without approval.

Decision of 286th meeting of Registration Board:-

Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

Accordingly, the case was referred to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:-

i. That M/s. Sharex Laboratory applied for the quota allocation of product ―Tracodil Syrup‖ (Reg.No.003158).

ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of ―Tracodil Syrup‖ (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of ―Tracodil Syrup‖ (Reg.No.003158) and 60ml (dated 27th October, 1988).

iii. That the approved pack size of the product ―Tracodil Syrup‖ (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).

iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product ―Tracodil Syrup‖ (Reg.No.003158) without approval.

v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.

vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, imcomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision of 289th meeting of Registration Board: -

In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue show cause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:

- Cancellation of registration.
- Suspension of registration.
- Prosecution in Drug Court

Accordingly show cause notice has been served to M/s. Sharex Laboratories, Sadiqabad.

Registration Board in its 295th deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

Discussion:

M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm and stated that firm was unaware about the approval of pack sizes of Tracodil Syrup (Reg.No.003158) as on initial registration letter no pack size was written. He has further stated that firm will submit all the relevant documents / approvals granted by DRAP regarding said product.

Decision:

Registration Board deferred the case for further deliberation after submission of documents as stated by representative of the firm

Sr. No.	Details of application	No. of Cases
A	Locally Manufactured Human Biologicals.	2
Total		15

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. Saadat Ali Khan	AD-II	1
2.	Mr. M. Zubair Masood	AD-III	1

A: Locally Manufactured Human Biologicals.

1. Local human Biological applied for registration by M/s Macter International Limited, Karachi deferred in 295th meeting of Registration Board.

The following product for the local manufacturing biological drug was considered in 246th Meeting of Registration Board held on 10-11th December, 2014 but later on the Registration Board in its 270th meeting advise the division of Biological drugs to come up with working paper in the next meeting. The final guidelines regulatory requirements of Biological drugs using rDNA technology has been approved in 278th meeting of Registration Board. As per initial Registration dossier the ready to fill bulk will be imported from Hangzhou Jiuyuan Gene Engineering Co., Ltd. (China) for local vial filling and packaging. The Detail is as under;

1.	Name of Manufacturer	M/s Macter International Limited,F-216, Site, Karachi
	Brand Name +Dosage Form + Strength	Macgrastim***300 mcg/1.2ml*** *(Filgrastim-Recombinant human granulocyte colony-stimulating factor*
	Composition	Each vial contains: Filgrastim…..300mcg/1.2ml
	Finished product specifications	BP Specification
	Pharmacological Group	Therapeutic Protein
	Shelf life	2 years when stored
	Products already registered in Pakistan	Grastim by CCL Pharma, Lahore.
	Type of Form Dy No & Date of application, Fee submitted	Form-5, Dy No.1118/2014(R&I) dated 10-10-2014 Rs. 20000 dated 16-09-2014
	Demanded Price / Pack size	Price: As per PRC Pack of 1's (Vial)

The firm has submitted data as per the said guidelines. The submitted documents are evaluated as under;

Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	Documents submitted by firm
The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Provided
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Provided
The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured	Provided & Evaluated below

either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	In China Filgrastim (rhG-CSF) is not included in products which require LOT Release Certificate.
The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Provided
The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same),visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application.	Physical Appearance Particulate Matter pH Osmolality, Immuno identification by western blotting, Protein Content by Lowry Method, Biological Activity by Invitro bioassay, Potency, Purity by Sodium Dodecyl Sulfate Poly-Acrylamide Gel Electrophoresis (SDS-PAGE), Purity by Gel Filtration HPLC, a. Endotoxin Test by Gel Clot Method**, Sterility Test,** Abnormal Toxicity **(on** NMRI mice)
The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided
The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Provided
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill)that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	The firm has submitted Supply Agreement between Macter International Limited & Hangzhou Jiuyuan Fene Engineering Company dated 24th July 2013 wherein it has been mentioned that the firm will provide advance notification to Macter and DRAP of any significant changes to process, specifications and analytical methods, product…. **(Point no.7c. Change Control of the agreement)**
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Layout plane submitted. The firm has also provided Commitment on its letter head mentioning the said statement.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Commitment provided on the letter head

If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Commitment provided on the letter head
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Commitment provided on the letter head

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	i. Molecular Weight by Reducing SDS-PAGE ii. **Assay for chemical structure by following methods** a. Sequencing for recombinant DNA b. UV Spectrum c. Composition of Amino Acids d. Peptide Mapping e. N-terminal sequencing of rhG-CSF by Edman degradation
Biological Activity	**In-vivo activity** by Activity of rhG-CSF in vivo (Effects of rhG-CSF on CY-induced myelo suppression in rhesus Monkeys): In-vitro activity by a. 3H-TdR assay , b. MTT assay using NFS-60 cell line
Immunochemical properties	a. Identification (by Western Blot) b. ELISA (Enzyme-linked Immunosorbent Assay)
Impurities	**Purity assay by following methods** a. Non-Reducing SDS-PAGE & Reducing SDS-PAGE b. Iso-electric focusing c. Reverse Phase HPLC d. SEC-HPLC (Size Exclusion Chromatography HPLC) e. Capillary Electrophoresis
Stability Studies	Stability studies are provided.
Non-clinical Studies	**In Vitro Pharmacodynamic Study:** Effect of rhG-CSF on the proliferation of normal mouse and human bone marrow cells in vitro Effects of rhG-CSF on Acute Radiation-induced Hematopoietic Injury in Mice **Toxicity study is provided but not comparative.**
Clinical Studies	A Comparative Study between Jilifen (rhG-CSF) Hangzhou Jiuyuan Gene Engineering Co., Ltd China and Gran (rhG-CSF) manufactured by Kirin Brewery Company, Japan in Hematological Malignancy **(Conducted in 15 hospitals in Shanghai from Mar to Jun 1998)**

Decision of 291st meeting Registration Board: Registration Board deferred the case for submission of following by the firm:

a. Comparative toxicity studies data under biosimilarity studies.
b. Clarification regarding the import of finished product from same source with same name.

For the point no. (a) the firm has submitted that since comparative clinical studies in humans are provided and proving similarity in toxicity, importance of comparative toxicity data in animals is of secondary in importance and is not critical or confirmatory nature and as per Chinese Biosimilar guidelines states that if Bio-similarity is proven by PK/PD and immunogenicity there is no need to do comparative toxicity in animals.

While the point (b), the firm has submitted that the finish product applied by them with the name brand name is from the different source and in the different dosage form i.e. PFS .And further it has been submitted by the firm that they will change the brand name of the finish product if required.

The original reply of the firm has been reproduced as under for ready reference and understanding.

a) *"Our case of Macgrastim 300mcg, liquid solution for injection was deferred in 291st DRB meeting of DRAP on the basis of comparative toxicity data in bio similarity studies, in this context we want to clarify that we have submitted comparative clinical trial in humans in which efficacy & safety (side effects & toxicity profile) are compared. (Refer to Vol.II annexure d.3 clinical study report page 1-7).*

b) *Since comparative clinical studies in humans are provided and proving similarity in toxicity, importance of comparative toxicity data in animals is of secondary in importance and is not critical or confirmatory nature.*

c) *As per Chinese Biosimilar guidelines states that if Bio-similarity is proven by PK/PD and immunogenicity there is no need to do comparative toxicity in animals.*

d) *Since robust comparative structural and quality data is given which suggests high similarity with innovator product (Refer to Macgrastim dossier as mentioned in annexure-d. biosimilarity study).*

e) *Since finished drug of same manufacturer is already registered in Pakistan and is marketed by AA pharma with brand name JILIFEN injection registration No.045618.*

f) *Accepting Dr. Sarfraz Niazi petition US FDA has accepted that if robust analytical data suggests similarity then comparative clinical trial data is unnecessary to prove similarity. (see attached recent US FDA draft guidelines on Insulin page 3, lines 95-107. Insulin and GCSF are similar size peptides of same class cytokines.*

g) *US FDA updated thinking reflects that requirement of even comparative clinical data can be waived while in our case comparative clinical trial data in humans is given and toxicity data in animals is provided but it is not comparative. As per current thinking of US FDA comparative toxicity in animals is of no importance. In Macgrastim case we have submitted robust comparative analytical, structural and human clinical studies and single arm extensive toxicity data in animals is also submitted which stands sufficient to prove bio-similarity. We request that our product Macgrastim solution for injection (300ug Filgrastim) may kindly be approved for registration.*

h) *Same product with same formulation is registered & marketed in china i.e. country of origin*

Second query was clarification regarding the import of finished product from same source with same name.

a) *We also want to clarify that Macgrastim prefilled syringes (PFS) & Macgrastim 300mcg, liquid solution for injection are two different dosage form and both of them are from two different sources. The source of Macgrastim prefilled syringes is BEIJING SL PHARMACEUTICAL.CO LTD while the source of Macgrastim vials containing liquid solution for injection is HANGZHOU JIUYUAN GENE ENGINEERING CO., LTD. As Macgrastim prefilled syringe was also applied by us for registration. We are waiting for some data from our source BEIJING SL PHARMACEUTICAL.CO LTD and we may change brand name if required.*

The case was considered in 295th meeting of Registration Board wherein the Board decided as follows:
"*Registration Board deferred the case for further deliberation in next meeting and advised DBER to bring up the details of all the cases which have already been approved on the basis of guidelines formulated in 278th meeting of Registration Board."*

In this context, it is submitted that till date following manufacturers are given registrations for local manufacturing in light of guidelines formulated in 278th meeting:

1. M/s Macter International, Karachi
    a. Momentum (Etanercept)
2. M/s BF Biosciences, Lahore

a. Eritrogen 2000IU PFS
b. Eritrogen 4000IU PFS
c. Eritrogen 10000IU PFS
d. Eritrogen 10000IU Vial

3. M/s Nextar Pharma, Karachi
    a. NP-Poetin 2000IU PFS
    b. NP-Poetin 4000IU PFS
    c. NP-Poetin 10000IU PFS

The locally performed test by each manufacturer for above products against the requirements of 278th meeting are tabulated as under:

Tests required as per 278th Meeting	**Tests performed by M/s BF Biosciences, Lahore for Eritrogen**	**Tests performed by M/s Nextar Pharma, Karachi for NP-Poeitin**	**Tests performed by M/s Macter International, Karachi for Momentum**
• Protein content • Appearance • pH • Osmolarity • Composition of key excipients including stabilizers (if formulation is same) • Visible/subvisible particles • Identity • Purity testing • In vitro biological activity • Sterility • Pyrogen content • Safety • Potency • **Toxicity** (with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques)	• Appearance • Leak test • pH • Extractable volume • Immuno characterization • Potency • Sterility • Bacterial endotoxins • Particulate matter. • Sialic acid content • Protein concentration • Peptide mapping • Identification (by SDS page) • Isoforms content • Dimers and related proteins of higher molecular mass • Abnormal Toxicity/ Safety	• Appearance • Particulate Matter a. Visible b. Sub-visible • Leak Test • Filling Volume • Identification by SDS-PAGE • Identification by Immunobloting by Western blot • pH • Protein Content • Purity by SEC HPLC • Residual Bacterial Endotoxins • Potency/ Biological activity a. In-Vitro b. In-Vivo • Sterility • Safety/ Abnormal Toxicity	• Appearance • Particulate Matter a. Visible b. Sub-visible • pH • Osmolality • Identification by SDS-PAGE • Identification by Immunobloting by Western blot • Purity by Gel Filtration Chromatography • Purity by Isoelectric focusing • Protein Content • Biological Activity by Cytotoxicity Inhibition Assay • Endotoxin Test by Gel Clot Method • Sterility • Abnormal Toxicity

The point of concern of Registration Board in 295th meeting was the In-Vitro Toxicity test mentioned in requirements. No local manufacturer has performed this test as per provided data and the same was not pointed out by DBER in Registration Board as the said test is not performed by the Biosimilar manufacturers of reference regulatory authorities and it is evident from the Quality part of EPARs of above formulations available on official website of EMA. The said test is performed in pre-clinical part, which was exempted in 278th meeting of Registration Board for local manufacturers as the said part is provided by bulk manufacturer. Moreover, to support the safety of their products, all the manufacturers have provided the results of In-Vivo Abnormal Toxicity Test which is not included in the requirements of 278th meeting.

Decision: Registration Board referred the case to Committee on Biological Drugs constituted in 273rd meeting of Registration Board for its recommendations on the requirements of toxicity studies and abnormal toxicity studies. Moreover, Registration Board nominated Lt. Gen. (R) Prof. Dr. Karamat Ahmed Karamat (HI-M, SI-M) as Chairman of said committee.

2. Nexfil Injection applied by M/s Nextar Pharma, Karachi.

M/s Nextar Pharma, Karachi had the registration of Nexfil injection as per following details:

Reg. No.	Name of Bulk Manufacturer	Brand Name & Composition	Packaging
077534	M/s Pooyesh Darou, Tehran Iran	Nexfil 300 Inj Each Prefilled syringe contains: Filgrastim…….300mcg (B.P)/ml	1 x 1 PFS

The registration letters was issued to the firm on 08-12-2014. Then the firm applied for the change in source of bulk from M/s Pooyesh Darou, Tehran Iran to M/s Shandong Kexing Bio-products Co., Ltd., China No. 2666 Chuangye Road, Mingshui Development Zone, Zhangqiu, Shandong and approval was granted on 17-02-2017. The aforementioned registration was granted exclusively for trial manufacturing of drug and not for sale in the open market. Now the firm has applied for the marketing permission of aforementioned products as per following details.

1.	**Name of Manufacturer/ Applicant**	M/s Nextar Pharma (Pvt.) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi. DML No. 000777 **Bulk Manufacturer:** M/s Shandong Kexing Bio-Products Co., Ltd., No. 2666 Chuangye Road, Mingshui Development Zone, Zhangqiu, Jinan, Shandong, China.
	Brand Name +Dosage Form + Strength	Nexfil 300 Inj
	Composition	Each ml contains: Each Pref-filled Syringe contains Filgrastim……..300mcg/0.5mL
	Finished product specifications	Nextar Specifications
	Approval status in Reference countries	Zarzio of M/s Sandoz Limited, UK
	Products already registered in Pakistan	Zarzio of M/s Novartis Pharma, Karachi
	Shelf life	24 months (2^0C-8^0C)
	Dy No & Date of application, Fee submitted	Dy. No. 7973, 23078, 10600 & 20579 Date: 10-06-2019, 08-11-2019, 11-05-2020 & 19-08-2020 Rs. 20000/- dated 23-11-2016
	Demanded Price/ Pack size	1's PFS/ As per SRO
	General documentation	Copy of cGMP dated 01-11-2019 valid for 01 year.

The firm has submitted the documents/data in the light of regulatory guideline for biological products approved in 278th meeting of Registration Board as per following details:

Sr. No.	Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	Documents submitted by firm
12.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Legalized copy of GMP certificate No. SD20190880 dated 22-02-2019 of M/s Shandong Kexing Bio-Products Co., Ltd., No. 2666 Chuangye Road, Mingshui Development Zone, Zhangqiu, Jinan, Shandong, China valid till 21-02-2024.
13.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Legalized FSC No. 2020-012 dated 30-07-2020 valid for two years.
14.	The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk	Details are included below.

	concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	
15.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (Not applicable).
16.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Provided.
17.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same), visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application.	The firm has submitted CoAs wherein the tests conducted are as under; i. Appearance ii. Particulate Matter iii. Leak test iv. pH v. Filling volume vi. Identification by RP-HPLC vii. Protein Content/ Assay viii. Purity by SDS-PAGE ix. Purity by Iso-electric focusing x. Related Proteins (HPLC) xi. Potency (Biological Activity) a. In-Vivo b. In-Vitro x. Sterility xi. Bacterial Endotoxins xii. Safety Test/ Abnormal Toxicity
18.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Provided
19.	The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided.
20.	The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Brazil, Indonesia, Paraguay, Philippines
21.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Provided.
22.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Provided.
Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.		
WHO Bio-similarity guidelines	**Data submitted by the firm**	

Quality Comparison Physicochemical characterization	**Physicochemical Characterization** i. N-terminal amino acid sequence ii. Peptide Mapping iii. Purity by Western-Blot Analysis iv. Purity by Capillary Isoelectric Focusing v. Secondary Structure by Circular Dichorism vi. UV Absorbance Spectroscopy vii. Fluorescence viii. Secondary Structure by Fourier Transform Infrared Spectroscopy (FTIR) ix. Free Cystein x. Mass Spectrum xi. Impurity Profile by SDS-PAGE xii. Impurity Profile by Size Exclusion HPLC xiii. Impurity by Analytical Ultracentrifugation xiv. Thermal Stability by Dynamic Light Scattering xv. Quantitative Impurities Analysis by RP-HPLC xvi. Impurities by Iso-electric focusing xvii. Charge Distribution by Ion Exchange Chromatography
Biological Activity	i. In-Vitro Biological Activity in NFS 60 cell. ii. In-Vivo biological activity in albino mice
Immunochemical properties	Receptor binding by Flow Cytometer.
Impurities	Impurities by SEC-HPLC.
Stability Studies	Comparative stability profiles to assess the degradation products.
Non-clinical Studies iii. In-vitro Studies iv. In-vivo Studies	• Comparative Local Tolerance testing after single administration in rabit • Comparative repeat dose toxicity study in Wistar rats for 28 days. • Comparative Toxicokinetic studies in Wistar rats over a period of 14 days. • Comparative Pharmacodynamic Study of G-CSF in Rhesus Mokey.
Clinical Studies	• Bioequivalence study report in healthy volunteers • Summary of comparative safety and efficacy study in treatment of granulocytopenia after the cancer chemotherapy.

Remarks of Evaluator (M. Zubair Masood):

- The initial registration letter was issued for 300mcg/ml while now the firm has applied for 300mcg/0.5ml. The firm was asked for clarification and they submitted that they are manufacturing 300mcg/0.5ml PFS.
- The firm submitted that Filgrastim injection is not available in any Pharmacopoeia and requested for Nextar specifications. Filgrastim Injection is available in Japanese Pharmacopoeia.
- The firm has only submitted Bioequivalence study report and summary of comparative safety and efficacy study. The firm was asked to provide the complete comparative clinical trial data. In response, the firm requested to hold the summary of comparative safety and efficacy study as it is not fulfilling the requirements of WHO Biosimilarity guidelines. Instead the firm submitted that the product was registered in China in 2002 and at that time comparative trials was not the requirement in China. The firm also submitted the "Requirements for registration and classification of biological products". The firm further submitted that the finished product of M/s Shandong Kexing Bioproducts Co. Ltd. is already registered in Brazil, Indonesia, Paraguay, Philippines and Pakistan.
- The above mentioned guidelines clearly states that clinical trials should be conducted for new drugs. The firm has not submitted the safety, efficacy data of their product. The firm has already been issued two letters but the application is still not complete.

Decision: Registration Board referred the case to Committee on Biological Drugs constituted in 273rd meeting of Registration Board for its recommendations on the requirements of toxicity studies and abnormal toxicity studies. Moreover, Registration Board nominated Lt. Gen. (R) Prof. Dr. Karamat Ahmed Karamat (HI-M, SI-M) as Chairman of said committee. However, the firm shall submit safety and efficacy data of the finished product of bulk manufacturer abroad.

Division of Quality Assurance & Laboratory Testing

CASE NO.01:- MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD ZOLERIC 20MG CAPSULES B.NO.18 MFG BY M/S GENIX PHARMA PVT LTD KARACHI

That Mr. Usman Hameed the then FID Quetta, forwarded the case vide letter No.12-15/06-DCA-Q (MB & Substandard)-1166 dated 06th April 2007. It was informed by Mr. Usman Hameed, that the then FID Mr. Muhammad Adnan Faisal Saim visited the premises of M/s Muhammadi Traders Natha Singh Street, Quetta on 23-11-2005 and took the sample Zoleric Capsules B.No.18 claimed to be manufactured by M/s Genix Pharma Pvt Ltd Karachi along with other samples of the purpose of test/analysis on prescribed Form-3.

02. That the then FID Quetta informed that sealed sample of above said drug along with other samples of drug was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F.5/DCA-QTA/Sample-3810 dated 24-11-2005 on form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB & RB Islamabad vide letter No.F.5/DCA-QTA/Sample-3811 dated 24-11-2005under section 19(3)(ii) of Drug Act 1976.

03. The FID Quetta submitted that the sealed sample as purported to be manufactured M/s Genix Pharma Pvt Ltd Karachi of said drug was also sent vide office letter No. F.5/DCA-QTA/Sample-3696 dated 25-11-2005 under section 19(3)(iv) and warrantor portion of said drug was sent to M/s Genix Pharma Pvt Ltd Karachi vide letter No.F.5/DCA-QTA/Sample-5057 dated 19-01-2006.

04. The Government Analyst CDL, Karachi declared the sample Zoleric Capsules B.No.18 Manufactured by M/s Genix Pharma Pvt Ltd Karachi is Substandard and Misbranded drug vide test report No.R.2649/2005 dated 17-04-2006.

05. The FID Quetta submitted that in the light of above Government Analyst, CDL, Karachi a show cause notice letter No.F.12-150/06-DCA(MB & Substandard)-820 dated 09-09-2006 was accordingly issued to M.s Genix Pharma Pvt Ltd Karachi for explaining the position in the matter of manufacturing and selling of above mentioned Misbranded and substandard drug. The FID Quetta further informed that the response of the above letter was not received in the office So the firm was issued a reminder vide letter No. No.F.12-150/DCA-QTAMB& S.S-1119 dated 09-03-2007. In response of the above letter of the office of FID Quetta reference No. GPPL-QC/024/07 dated 03-04-2007 according to which **the firm intends to get the sample retested from Appellate Lab at their own cost. The firm has violated section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 as per above referred test of Government Analyst CDL Karachi.**

06. The firm replied vide their reference letter no. GPPL-QC/025/07 dated 03-04-2007 wherein they submitted the names of owner and technical staff of the firm as follows formanufacturing of **Capsule Zoleric 20mg Batch No. 18 mfg. date – 12/04**:

i. Managing Director – Chaudhary Muhammad Israr Sharif
ii. Manager Quality Control –ZafarUllah Baig
iii. Manger Production – Munsif Ali Qureshi

07. Proceedings and Decision of 291st Meeting of Registration Board:

On the request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case presented before the Registration Board in its 291st Meeting on 4th September, 2019 and the Board after detailed deliberation decided **to issue the show cause notice to the firm (M/s Genix Pharma Pvt. Ltd., Karachi) for violating section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 and its following responsible persons**:

i. Managing Director – Chaudhary Muhammad Israr Sharif
ii. Manager Quality Control – Zafar Ullah Baig
iii. Manger Production – Munsif Ali Qureshi

08. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

> ***"****That Federal Inspector of Drugs, Quetta during inspection of M/s Muhammadi Traders Natha Singh Street, Quetta on 23-11-2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976****:-***
>
> | | |
> |---|---|
> | ***Name of Product:*** | *Zoleric 20mg Capsules* |
> | ***Batch No.*** | *18* |
> | ***Manufacturing Date:*** | *07-05* |
> | ***Expiry Date:*** | *08-07* |
> | ***Manufacturer:*** | *M/s Genix Pharma Pvt Ltd Karachi* |
>
> *2. The Federal Government Analyst, vide test/analysis report No.2649/2005 dated 17th April, 2006 had declared the sample as of "****Misbranded &Sub-Standard****" quality* ***(Copy Annexed)****.*
>
> *3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:*
>
> *[…]* ***to issue the show cause notice to the firm (M/s Genix Pharma Pvt. Ltd., Karachi) for violating section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 and its following responsible persons****:*
>
> *i. Managing Director –Chaudhary Muhammad Israr Sharif*
> *ii. Manager Quality Control – ZafarUllahBaig*
> *iii. Manger Production – Munsif Ali Qureshi.* ***[…]***
>
> *4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.*
>
> ***i. Prosecution in the Court of competent jurisdiction.***
> ***ii. Cancellation/suspension of registration.***
> ***iii. Any other action the Board may deem fit under the law.***
>
> *5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.****"***

Proceeding and Decision of 292nd meeting of Registration Boardheld on 01st – 02nd October, 2019.

09. Mr. Maqsood-Ur-Rehman, AGM Quality Assurance, Genix Pharma Pvt. Ltd. 44, 45-B, Korangi Creek Road, Karachi appeared before the Registration Board to plead the instant case before the Registration Board. The representative of firm submitted a written reply before the Board. The reply is reproduced as under:

> *"With reference to your letter No.F.03-41/2019-QC (291-DRB) dated 19.09.2019, received in Genix Pharma on 26.09.2019, wherein, the product Zoleric 20mg Capsule (Esomeprazole), batch No. 018 mfg. date 07-2005 was declared as misbranded and substandard vide test analysis report 2649/2005 dated 17.04.2006.*
>
> *Genix Pharma (Private) Limited was founded with the vision to help and provide top quality and affordable medicine for all those in need. Since inception, Genix has grown from being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena, the company's aim to become the benchmark in the pharmaceutical industry.*

Genix Pharma is making an ever-increasing contribution to the export of Pakistan by exporting medicines to more than 20 countries including, South Asian, North American, African and Russian Countries. Genix is strongly committed to its responsibility towards community and patients. Genix's products bring a promise of QUALITY, and ensure smooth and flawless operations at its facility with local manufacturing in compliance with global quality standards which are strictly maintained and followed meticulously at every level in the process of manufacturing.

Genix Pharma believes on continual improvement and for that we enhance our cGMP according to National and International Guidelines, our sterile area is developed with high class imported prefabricated sheets, we have developed dedicated and well-equipped Quality Control laboratory and Currently (August & September- 2019) our QMS have certified as cGMP compliant by the Ministry of Health Uzbekistan and Azerbaijan and also many more countries.

We would like to inform that FID Quetta send letter for the case mentioned above on 09.09.2006, which was unfortunately not received at Genix Pharma Pvt Ltd., for that FID sent us reminder letter on 09.03.2007, upon receiving that letter Genix Pharma sent reply letter number GPPL/QC/024/07 & GPPL/QC/025/07 dated 03-04-2007 in response of reminder letter. After that we did not receive any letter in the matter subjected above and it seems that our position is clear and case has been closed. Now after 12 years we receive this show cause notice and personal hearing letter.
We request you to kindly consider the above reference. We look forward to the pleasure of hearing from you favorably.

Decision of 292nd meeting of Registration Board.

10. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

- **A. Suspension of the registration of Zoleric Capsules 20mg (Reg. No. 039087) for a period of Six (06) months or till the verification of root cause analysis, CAPA, product development data and satisfactory report by the panel whichever is later.**
- **B. Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel:**
  - **i. Dr. Rafiq Alam Khan, Member Registration Board**
  - **ii. Area Federal Inspector of Drugs**
  - **iii. Assistant Director (I&E)**
- **C. In the light of panel inspection report, Registration Board will decide the fate of the product.**
- **D. Fresh Sampling from the premises of firm and one sample each from the market in area jurisdiction of five (05) regional offices of DRAP.**

The above said decision of the Board was communicated to the panel vide letterNo.F.0346/2019-QC (292-DRB) dated 12-11-2020.
In response to the above said letter area FID, DRAP, Karachi vide reference No.F.000351/2020-FID-I (K) dated 30-07-2020 forwarded the report of M/s Genix Pharma (Pvt) ltd., Karachi.
It is submitted that annexure were attached with the report and there was no information about the fresh sampling of the drug.
The area FID, DRAP, Karachi was requested to provide/ comply with the decision of the Board for further processing of the case.
In response to the above said letter area FID, DRAP, Karachi vide reference No.F.000351/2020-FID-I (K) dated 07-09-2020 submitted that the report was sent along with annexure vide this office letter, however, photocopies of the same along with root cause analysis, CAPA, are again attached herewith.

He further submitted that fresh sampling of the was done at the time of inspection and sample was sent to CDL, Karachi for test analysis. The FGA, CDL, Karachi declared the said sample as of standard quality vide test report No.KQ.200/2020 dated 01-08-2020.

The inspection report provided by the FID, DRAP, Karachi is reproduced as under;

*Inspection of M/s Genix Pharma (Pvt.) Ltd. Situated at Plot 44-45-B, Korangi Kreek Road Karachi was conducted on 23rd July 2020 with reference to DRAP letter No.F.3-46/2019-QC (292-DRB) dated 12th November 2019 (**Annex-A**), for product specific inspection including the verification of product development data and confirmation of CAPA of the product Cap. Zoleric 20mg (Esomeprazole Magnesium), Registration No. 0319087, Batch No. 18, declared as "**Mis-Branded**" and "**sub-standard**" as per CDL test/analysis report No.2649/2006 vide No. F.5-3/2006-CDL/S-775 dated 17th April 2006 (**Annex-B**), on the basis of :*

1. *The inner most label does not contain English/urdu version of the instruction as required under rule 3(h)(iii) of the Drugs (Lebelling & Packing) Rules 1986 and Section 3(s)(i) & 3(s)(ii) of the Drugs Act 1976*
2. *Weight Variation*

Following panel of experts inspected the firm:-

i. *Prof. Dr. Rafeequ Alam Khan, Member Registration Board*
ii. *Dr. Najam-us-Saquib, FID (Area)*
iii. *Dr. Kirshan AD (I&E)*

The panel has gone through following areas to verify the reasons for manufacturing of Mis-branded and substandard drug product Cap. Zoleric 20mg (Esomeprazole Magnesium), Registration No. 0319087, Batch No. 18:

1. *Raw Material Store.*
2. *Production / filling facility of Capsule Section.*
3. *Quality Control Lab.*
4. *Quality Assurance*

Following observations were noted during the course of inspection.

1. Raw Material Store

i. *M/S Genix Pharma (Pvt.) Ltd. had only one approved source for the purchase of API (Esomeprazole pallets containing Esomeprazole Magnesium Trihydrate) from M/S Titan Pharma India (Pvt.0 Ltd., Mumbai India (**Annex-C**). After that, the firm has switched to a local source namely, M/S Surge Laboratories (Pvt.) Ltd, 10KM Faisalabad Road, Bikhi, District Sheikhupura and obtained DRAP approval vide letter No. F.33-PRVC/2019(PR-I) dated 23rd October 2019 (**Annex-D**).*
ii. *The log book record shows that accurate quantity of Esomeprazole pellets and other excipients, as per material issue note (MIN), was received for the manufacturing of Cap. Zoleric 20mg Batch No.18 (**Annex-D**).*
iii. *Testing record of the Cap. Zoleric 20mg Batch No.18, shows that weight variation results were within the reference limits (**Annex-E**).*
iv. *Storage conditions of RMS were found satisfactory.*
v. *The manufacturing order issued by the production department was for 50000 capsules as per available record (**Annex-F**).*
vi. *The process of manufacturing for this particular product is blending/mixing and filling steps (**Annex-G**).*
vii. *The Manufacturing facilities match with the batch size.*
viii. *The batch was filled on manual capsule filling machine in 2006.*

2. Manufacturing Facility of Capsule Section: -

i. *At present, the firm have two blenders, one of 200 Kgs another 500kgs and also has an automatic filling machine and blister machines.*
ii. *The product involves coated pallets and based on blending/mixing of Esomeprazole pellets with neutral pellets.*

iii. *Logbook record was checked and found satisfactory. In process testing was performed during and after filling. The record was compared with the logbooks and found satisfactory.*

3. Quality Assurance: -

*The catch cover and inner most label has been replaced and the inner most labets are now bearing both the English/Urdu versions (**Annex-I**).*

4. Quality Control Facility: -

i. *The Firm followed inhouse specifications at the time of testing of the batch in question and used UV spectrophotometric method and at present firm has switched the specifications to USP and obtained approval vide DRAP letter No. F. 289-RB/2019 (PR-I) dated dated 4th July 2019 (**Annex-J**). The record shows that the firm is using HPLC method for the product in question testing of this product as per USP.*

ii. *Testing record of said product was available and found satisfactory.*

iii. *SOPs of testing were found validated.*

iv. *The management of the firm has provided the copies of the testing reports of the Cap. Zoleric 20mg that were tested by the Central Drugs Laboratory (CDL), wherein the same product was declared as of **"Standard Quality"** vide CDL test/analysis reports No. 1387/2008-OA dated 18th December 2018 and KQ.273/2019 dated 20th may 2019 (**Annex-J & K**).*

Conclusion: -

Keeping in view the people met, documents reviewed including manufacturing, testing and ware house record and finding of the inspection, the firm is found complying GMP as of today. The manufacturing of the product in question was found satisfactory and in accordance with the SOPs. Testing of the product Cap. Zoleric 20mg was also according to in house specifications which is now switched to USP specification after DRAP approval. The product was declared substandard due to non-compliance of the rule 3(h)(iii) of the Drugs (Labelling & Packing) Rules 1986 and Section 3(s)(i) & 3(s)(ii) of the Drugs Act 1976 and non-compliance of the weight variation test.

Firm has switched from manual filling machine to an automatic capsule filling machine with more in-built accuracy and replaced the inner most labels as per referred labelling Rules.

Proceeding & Decision of 296th Meeting of Registration Board.

The Case was presented before the Board and Board after detailed deliberations and discussions decided to resume the production of the product (Zoleric Capsules 20mg (Reg. No. 039087) which was under suspension since the decision of Registration Board in its 292nd meeting held on 01st – 02nd October, 2019).

CASE NO. 2:- MANUFACTURE AND SALE OF MISBRAND AND SUBSTANDARD NAMELY FREESIA TABLETS B.NO.F03R2

That Mr. Syed Abdul Saleem the then FID Quetta, forwarded the case vide letter No.5-75/2006.DCA(Q)U-R-1788 dated 15th November, 2008. The then FID informed that he visited the premises of M/s Shan Enterprises Quetta on 21-09-2005 and took samples of drug namely Freesia Tablet B.No. F03R2 labeled to be manufactured by M/s Karachi Chemical Industries, Karachi along with other samples of drug for the purpose of test analysis under the Drug Act 1976.

02. That the then FID Quetta informed that the sealed sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F/5/DCA-QTA/Sample-3548 dated 23-09-2005 on form-4 and a portion of the said drugs also sent to the Chairman CLB Islamabad vide letter No.F.5/DCA-QTA/Sample-3547 dated 23-09-2005.

03. That the then FID Quetta informed that the Director, CDL, Karachi vide his test report No.2279/05 dated 27-03-2006the sample of Freesia Tablet B.NO. F03R2 labeled to be manufactured by M/s Karachi Chemical Industries Karachi as **Misbranded/Substandard**.

04. The then FID, Quetta informed that in the light of Government Analyst, CDL, Karachi a show cause notice vide letter No.12-118/2006 DCA (Q)-MB.S. S-177 was accordingly issued to M/s Karachi Chemical Industries Karachi explaining the position in the matter of manufacturing and selling of the above mentioned Misbranded and substandard Drug. In response of the above letter No.F.12-118/2006 DCA Q (MB.SS-177 dated 22-04-2006the firm submitted reply.

05. The firm have violated section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi. The then FID, Quetta solicited the approval for prosecution in the Drug Court.

06. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of **Freesia Tablet Batch No. F03R2**withmanufacturing date 07/05:

i. Production Incharge – Zafar Khursheed
ii. Quality Control Manager – Muhammad Irshad
iii. Managing Director – Saboor Ahmed

07. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID (Q) K dated 05th August 2019, the case was placed before the Registration Board. The Board after detailed deliberation decided to issue the show cause notice for violating section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi against following responsible person(s) of firm (M/s Karachi Chemical Industries Karachi):

i. M/s Karachi Chemical Industries Karachi through its MD
ii. Production Incharge – Zafar Khursheed
iii. Quality Control Manager – Muhammad Irshad
iv. Managing Director – Saboor Ahmed

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:

a. Prosecution in the Court of competent jurisdiction.
b. Cancellation/suspension of registration.
c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

08. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

*That Federal Inspector of Drugs, Quetta during inspection of M/s Shan Enterprises Quetta on 21-09-2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976**:-***

Name of Product: *Freesia Tablet*

Batch No.	*F03R2*
Manufacturing Date:	*07-05*
Expiry Date:	*01-08*
Manufacturer:	*M/s Karachi Chemical Industries Pvt Ltd., Karachi*

*2. The Federal Government Analyst, vide test/analysis report No.2279/2005 dated 27th March, 2006 had declared the sample as of "**Misbranded &Sub-Standard**" quality **(Copy Annexed)**.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

> *[…] to issue the show cause notice for violating section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi against following responsible person(s) of firm (M/s Karachi Chemical Industries Karachi):*
>
> *i. M/s Karachi Chemical Industries Karachi through its MD*
> *ii. Production Incharge – Zafar Khursheed*
> *iii. Quality Control Manager – Muhammad Irshad*
> *iv. Managing Director – Saboor Ahmed.* ***[…]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.

Proceedings and Decision of 292nd Meeting of Registration Board held on 01st-02nd October, 2019

09. That None appeared on behalf of the accused before the Board (neither in person nor by any attorney/pleader) nor submitted any written reply to the show cause notice till 01st October, 2019.

10. The Board decided to granted last opportunity of personal hearing to the accused persons before the Registration Board in its upcoming meeting with direction that no further adjournments will be granted.

11. The decision of the Board as communicated to accused persons vide letter no. F. 03-46/2019-QC (292-DRB) dated 12.11.2019.

12. The reply of the firm M/s Karachi Chemical Industries (Pvt.) Ltd., F/25, Estate Avenue, SITE, Karachi-75730 is reproduced as under:

"Respected Sir,

Please refer to your letter No.F.03-41/2019 Q.C (291-DRB) Dated 19thSeptember, 2019 and this office letter No. Nil dated 25th September, 2019 along with copy of doctor prescriptions.

IT IS VERY STRANGE THAT THIS CASE IS PENDING FOR THE LAST 13 YEARS

It is submitted that this case was placed on the Agenda of the meeting No.292 held on 1stOctober, 2019. It is crystal clear from the Agenda that this case was at Serial No.6 which was not scrutinized by any person/ authority which is against the natural justice. It is clearly mentioned on agenda (copy enclosed)

"FIRM SUBMITTED REPLY"

Unfortunately, the Agenda of the meeting shows that one sided facts submitted by the Federal Drug Inspector and view point of the firm has not been included in the Agenda of the meeting. The fact of the case is as under.

In response of Federal Drug inspector letter No F-12-118/2006/DCA-Q (MB255)77 Dated 22nd April 2005 we replied vide letter dated 20.5.2006 by the firm (Copy enclosed) CHALLENGING THE REPORT.

Again, we received letter No. F.3-75/2006 QC dated 30-12-2008 from Secretary, Drug Registration Board, Government of Pakistan, Ministry of Health, Islamabad and promptly replied in detail vide our letter dated 21-1-2009, CHALLENGING TEST REPORT (copy enclosed).

That the Federal Inspector of the Drug Inspected the business premises of M/s Shan Enterprises Quetta on 21.9.2005 and took the sample of drug namely Tab. Freesia B.NO.F03R2 manufacturing date 7/2005 and expiry date 1/2008 manufactured by M/sKarachi Chemical Industries, Karachi for the purposes of Test/analysis.

CDL REPORT

That the Government Analyst Central Drug Testing Laboratory, Karachi vides Test Report No. 2279/2005 dated 27th March, 2006 declared the drug Sub-standard/Misbranded. Whereas the drug chemically is of standard quality 97.74% and limit is 90-110%. The Sample portion of this product was received in the Central Drug Testing Laboratory, Karachi on 10-10-2005 AND REPORTED ON 27™ MARCH, 2006 AFTER 5 MONTHS AND 17 DAYS. Which is contrary of Section 22(2) of Drugs Act, 1976? Furthermore, no extension has been taken by the Drug Inspector or Government Analyst from the competent authority (copy enclosed).

SECTION 22(2) IS GIVEN AS UNDER FOR PERUSAL OF HONOURABLE BOARD.

> *"The Government Analyst, as far as my be , shall submit the report referred to in the Section (1) within sixty days of the receipt by him of the sample of the drug and if he is not able to do so for reason beyond his control shall communicate the reasons to the Inspector in writing and shall endorse its copy to the (Central Licensing Board or, as the case may be , the Registration Board or the Provincial Quality Control Board) who shall have the sample tested from the same or any other Government Analyst or a Government Drug Testing Laboratory or any other Laboratory and shall ensure the receipt of result of such test and analysis within further period as may be prescribed and shall make the test report available to the Inspector for further action".*

On receipt of Test Report, we have checked the retention sample and found of standard quality with reference to Assay, Disintegration and other relevant tests.

That the Test Report of the Government Analyst Central Drug Testing Laboratory is not reliable as Government Analysis while assay for Pantoprazole mentioned Capsule, where as our product is Tablets.

That on receipt of Test Report we had challenged the test report within prescribed period. The sample has been expired on 1/2008 but the report of National Institute of Health has not been received so far. The sample has been expired on 1/2008.and the report of Applet Laboratory has not been received so far.

No. Warrantor Portion has been sent to us required under Section 19(3) of the Drugs Act, 1976 till to date.

As far as the Misbranded drug is concerned the Deputy Drug Controller (Q, C), Government of Pakistan, Ministry of Health, Islamabad No. F.3-15/205 QC dated 15 March, 2007 in a letter addressed to Director/Govt: Analyst Central Drug Laboratory, Karachi states:-: Since no punitive action under the Drugs Act, 1876 is being taken on the misbranded reports, you are advised not to comment on the Packaging and Labeling Rules and confined only to the protocols (Analysis) of the test performedtile this issue is sorted out or amendments are made in the relevant Rules."

Keeping in viewl3 years old case and the above facts it is requested that Honorable Board taking lenient I sympathetic consideration file this case. This firm was established in 1976 and serving the ailing people of the country from that date.
Yours sincerely
For Karachi Chemical Industries (Pvt.) Ltd"

Proceedings and decision of 293rd meeting of the Board:

4. That Mr. Saboor Ahmed (42201-7842077-5), Managing Director, M/s Karachi Chemical Industries (Pvt.) Ltd., F/25, Estate Avenue, SITE, Karachi-75730 appeared on behalf of M/s Karachi Chemical Industries (Pvt.) Ltd., F/25, Estate Avenue, SITE, Karachi-75730 to plead the instant case in the light of written reply, wherein they challenged the test report of CDL, Karachi U/s 22(4) of the Drugs Act, 1976 and requested to get their sample re-tested from Appellate Laboratory (NIH, Islamabad).

5. Registration Board deliberated that despite of request of the firm for re-tested from Appellate Laboratory (NIH, Islamabad), the then FID Quetta requested for prosecution against the firm and no clarification was obtained from FID Quetta by defunct DCA, MoH for not recommending for re-testing as required by the firm.

14. The Board after detailed discussion, deliberations, considering the facts of the case and stance of representative of the firm, decided as under:

ii. Constituted the following panel to conduct a thorough cGMP inspection of product in question (Freesia Tablet) and Take fresh samples for test/analysis purpose:

a. Dr. Rafiq Alam Khan, Member Registration Board.
b. Area FID, Karachi.
c. Affan Ali, AD-CDL.

The above said decision was communicated to the panel vide letter No. No.F.03-65/2019-QC (293RB) dated 22-04-2020.

FID-III, DRAP, Karachi vide reference No.F.1.5-14/20017-FID (K)-iii dated 21-08-2020 forwarded the inspection report and is reproduced as under;

Name Of the manufacturer	*M/s Karachi Chemical Industries (Pvt) Ltd*
Address	*Plot no. F-25. Estate Avenue. S.I.T.E.. Karachi*
Name Of Owner/Directors	1. *Mr. Saboor Ahmed. Managing Director* 2. *Ms. Munira Ahmed (Chief Operating Officer)*
Name of Production Incharge	*Mr. Hafiz Ghulam Haider*
Name of Quality Control Incharge Name of Quality Assurance Manager	*Mr. Muhammad Ejaz* *Mr. Jameel Ahmed*
Name Of Inspectors	1. *Dr. RafeeqAlam Khan. Dean Faculty of Pharmacy. Ziauddin University. Karachi* 2. *Mr. Syed Hakim Masood. Area Federal Inspector of Drugs, DRAP. Karachi.* 3. *Dr. Affan Ali Qureshi. Assistant Director. CDL, DRAP. Karachi.*
Date of Inspection	*18lbAugust, 2020*

Focus/ Scope of inspection:

The panel inspection of the firm is conducted in compliance to the directions contained in DRAP. Islamabad letter no. F. 03-65/2019-QC (293-R13) dated 22nd April, 2020.

Brief Introduction of the firm:

The-firm is involved in manufacturing of finished pharmaceutical products, its packaging, quality control testing and release for market under valid Drug Manufacturing License no. 000048 (By way of formulation).

Proceedings of inspection:

The inspection is initiated with a brief presentation by the firm's representative. It was informed that the product in question "Freesia Tablets" registered under Registration no. 032221 was granted change in name "Xantamep" vide DRAP, Islamabad letter no. F.6-10/2005-Reg- II(s)Vol-IV dated 20th May, ***2008(Annexure-A).***

Following areas were inspected by the panel:

Change room:

Firm.has provided separate change rooms for male and female officers and officials for entering into production premises. Requisite change over facilities were also found provided.

Raw material store/ Warehouse:

Dedicated general pharmaceutical raw material store is provided as per the approved lay out plan. Receiving bay is maintained with double door system. After receiving area, yellow racks are provided defining the quarantine area. Released materials are found placed in controlled temperature environment.

Dispensing Area:

Dispensing booths equipped with laminar flow is provided in a separate area with requisite controls. Material and personnel flow are separately provided. The dispensed materials are moved in dispensed cages to the respective production areas. Documentation and labeling of this area was found available.

Packaging Material Store:

Packaging materials are received from different entrance and are store in a dedicated area with proper well-defined quarantine and release area.

Production:

Freesia (Formerly)/Xantamep (currently) Tablets are manufactured in the General Pharmaceuticals Tablets manufacturing section. Firm manufactures only one product at a time in tablet section, minimizing the risk of cross contamination.

Tablet Section:

This section is further divided into following dedicated areas provided with HVAC system.

Mixing area:

Mixing equipments were found properly installed with status label. Slugging machine is also found available in the same area. Documents related with this area activity were also available.

Granulation area:

The area is found managed in hygienic condition at the time of inspection. No production activity was under progress. Equipment's were found properly labeled according to the status.

Compression Area:

Three dedicated compression cubicles are provided for compression activity. Analytical weighing balances are also provided for carrying out timely weight variation lest. BMR has proper sheet for recording of the same in this area.

Coating Area

Three accela coating pans are provided in the coating area. Proper exhaust ducts are also attached. Equipments bear proper status label.

Fluid Bed Dryer Area:

A 100kg capacity FBD is found installed on the floor in separate area. Behind this area a small equipments washing area is also provided with proper separation. It was learned that the firm has dedicated bags separate for each product.

In-p rocess La borato ry:

The firm has provided weighing analytical balance, new disintegration apparatus and hardness tester, vernier caliper and friabilitor for carrying out in process checks of the under-process tablets. The records of the same are also seen available.

Blistering and packing areas:

Firm has installed additional blistering machine with better controls. Batch number is now seen to be engraved as per the company's policy of recording of the batch number on primary carton and strip. The blisters are transferred through the conveyor belt for primary and secondary packing.

Finished Goods-ware House

Samples of Xantamep 40 mg Tablets were drawn on prescribed Form-3 by the area FID.

Quality Control

The laboratory is equipped with necessary equipments updated from time to time in last five years for carrying out test/ analysis of Xantamep/ Freesia Tablets. Dissolution apparatus, disintegration apparatus and 11PLC log books/ SOP's were seen and found in order.

Quality Assurance

The firm has developed basic quality assurance system. SOP's for process, procedures and operating instructions were seen available.

Recommendations for further improvement:

1. *Firm must expand the team and role of quality assurance system. The in-process tests , frequency shall also be increased.*
2. *Compendia Analytical methods required to be verified and Non Pharmacopeial methods must be validated properly.*
3. *Re-visit the stability plan and Up- grade high speed latest production equipments, as well as floor of the manufacturing area.*

Conclusion:

Keeping in view the management's commitment towards continuous improvements and up- gradation of production/ quality control and quality assurance system the panel is of the view that firm has addressed the issues related with the manufacturing, labeling/ printing and testing of Freesia/Xantamep Tablets. Addressing the above said recommendations will further improve the quality of tablets produced in this section of the firm Ms. Karachi Chemical Industries (Pvt.) Ltd., S.I.T.E., Karachi.

Proceeding & Decision of 296th Meeting of Registration Board.

Keeping in view the compliance report submitted by area FID, Karachi the Board was apprised regarding the compliance of its earlier decision."

The meeting ended with the vote of thanks to and from the Chair.

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